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UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
SAN FRANCISCO DIVISION

MARK HABELT, Individually and on Behalf of All Others Similarly Situated, Plaintiff, v. IRHYTHM TECHNOLOGIES, INC., *et. al.* Defendants.	CASE NO.: 3:21-CV-00776-EMC **CLASS ACTION** Hon. Edward Milton Chen **AMENDED COMPLAINT FOR VIOLATIONS OF THE SECURITIES LAWS** **JURY TRIAL DEMANDED**

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TABLE OF DEFINITIONS

Term or Acronym	Definition
AECG	Long-term Ambulatory Electrocardiogram Device
AMA	American Medical Association
Bardy	Bardy Diagnostics, Inc.
BioTelemetry	BioTelemetry, Inc.
CAM patch	Bardy Diagnostics, Inc.'s Carnation Ambulatory Monitor patch
CardioNet	CardioNet, Inc.
CEO	Chief Executive Office
CFO	Chief Financial Officer
CMS	Centers for Medicare and Medicaid Services
Class Period	August 4, 2020 to July 13, 2021
Company	iRhythm Technologies Inc.
Complaint	Amended Complaint
Coyle	Defendant Michael Coyle
CPT	Current Procedural Technology Codes
Devine	Defendant Douglas Devine
Dr. Freeman	Dr. L. Neal Freeman
ECG	A conventional electrocardiogram
Exchange Act	The Securities Exchange Act of 1934
FDA	United States Food and Drug Administration
Hill-Rom	Hill-Rom, Inc.
IDTF	Independent Diagnostic and Testing Facility
Indirect allocator	The standardized allowance CMS allows companies to recoup in reimbursement rates based on the historical ratios of indirect-to-direct costs, clinical labor costs, and work performed by physicians.
Individual Defendants	Defendants Kevin King, Michael Coyle, and Douglas Devine
iRhythm	iRhythm Technologies Inc. or the Company
IRTC	The ticker symbol for iRhythm's common stock traded on the NASDAQ.
King	Defendant Kevin M. King

Lead Plaintiff	Lead Plaintiff Public Employees' Retirement System of Mississippi
LifeWatch	LifeWatch Services, Inc.
MAC	Medicare Administrative Contractor
MCDA	Muller Consulting & Data Analytics, LLC
MCOT	Mobile Continuous Outpatient Telemetry
Muller	James Muller
Novitas	Novitas Solutions Inc.
PCBAs	Printed Circuit Board Assemblies
PE	The Medicare Physician Fee Schedule Practice Expense
PE rates	Payment rates established by CMS' standard cost methodology for services based on actual, direct costs of providing a service and a standardized fixed amount for indirect costs.
PFS	CMS' Medicare Physician Fee Schedule
Plaintiff	Lead Plaintiff Public Employees' Retirement System of Mississippi
Preventice	Preventice Solutions Inc.
Proposed Rule	Center for Medicare and Medicaid Services' proposed rule for the PFS applicable in 2021, released on August 3, 2020
R&D	Research and Development Expenses
RUC	The AMA's Resource-Based Relative Value Scale Update Committee
SEC	U.S. Securities and Exchange Commission
SG&A	Selling, General and Administrative Expenses
Zio XT	The Zio XT patch or iRhythm's core product

Lead Plaintiff Public Employees' Retirement System of Mississippi (referred to herein as "Lead Plaintiff" or "Plaintiff"), individually and on behalf of all other persons similarly situated, by its undersigned attorneys, for its Amended Complaint (the "Complaint") against Defendants (defined below), alleges the following based upon personal knowledge as to those allegations concerning Lead Plaintiff and, as to all other matters, the investigation conducted by and through its attorneys, including, among other things, a review of Defendants' public statements and filings made with the U.S. Securities and Exchange Commission (the "SEC"), wire and press releases either issued by or regarding iRhythm Technologies Inc. ("iRhythm" or the "Company"), analysts' reports, information obtained from experts on coding, coverage and reimbursement rates associated with the Centers for Medicare and Medicaid Services ("CMS"), including Dr. L. Neal Freeman ("Freeman") and James Muller ("Muller") of Muller Consulting & Data Analytics, LLC, facts disclosed in the merger litigation between Bardy Diagnostics, Inc. ("Bardy") and Hill-Rom, Inc. ("Hill-Rom") in the Delaware Chancery Court, and other information obtainable on the internet. Lead Plaintiff believes that substantial evidentiary support exists for the allegations set forth herein after a reasonable opportunity for discovery.

INTRODUCTION

1. This is a federal securities class action on behalf of a class consisting of all persons who purchased or otherwise acquired iRhythm's common stock between August 4, 2020 and July 13, 2021, both dates inclusive (the "Class Period") seeking to recover damages caused by Defendants' violations of the federal securities laws and pursue remedies under Section 10(b) and 20(a) of the Securities Exchange Act of 1934 (the "Exchange Act") and SEC Rule 10b-5 promulgated thereunder.

2. iRhythm is a digital healthcare company that focuses on providing long-term ambulatory electrocardiogram ("AECG") devices that purport to diagnose cardiac arrhythmias. Unlike traditional devices that usually provide between 24 and 48 hours of monitoring, AECG devices can provide up to 14 days of electrocardiographic data that is scanned and analyzed by the Company's cardiac technicians, and then presented in a report to a doctor for diagnosis. iRhythm derives virtually all of its revenue from its core product, the Zio XT patch (hereafter the "Zio XT"),

a water-resistant wearable patch-based biosensor incorporated with a monitor that is affixed to a patient's chest. While the Company aspires to develop and market a more advanced monitor that provides real-time monitoring, it has been unable to gain a foothold in the market for more sophisticated devices. As a result, iRhythm relied upon the Zio XT for over 85% of its total revenue.

3. Throughout the Class Period, all of the Company's Zio XT revenue was directly or indirectly tied to Medicare reimbursement rates. Accordingly, it was vital that Defendants were forthright with iRhythm investors about rate negotiations and the factors impacting those rates. At least 25% of the Company's total revenue was tied to servicing Medicare patients, and was directly impacted by Medicare reimbursement rates. The remaining sales to commercial payors were indirectly tied to Medicare reimbursement rates. Commercial payors typically pay between 1.5 times to 2 times the rate set by CMS in a Medicare Physician Fee Schedule ("PFS") released annually. Moreover, the economic literature and a consensus of experts, including the opinions of Lead Plaintiff's expert, Dr. Freeman, confirm that commercial payors renegotiate rates as a multiple of the effective Medicare rate. Hence, if CMS reduces the reimbursement rate for any medical device or service in the PFS, then commercial rates also reduce proportionally as they are renegotiated over the following one to three years based on the going rate for Medicare reimbursement.

4. Medicare reimbursement rates are set using Current Procedural Technology codes ("CPT codes"), and CMS oversees reimbursement policy, including the adoption and pricing of CPT codes for medical services. Before the Class Period began, CMS delegated the pricing authority for AECG devices to a local Medicare Administrative Contractor ("MAC") known as Novitas Solutions Inc. ("Novitas"). Initially, Novitas set the reimbursement rate for the Zio XT at $311. However, Defendants knew that this initial rate set by Novitas was at risk because it was temporary, was criticized by industry experts, and was dramatically out of line with the rates set by virtually all other MACs for similar products.

5. On August 3, 2020, after significant lobbying by iRhythm and medical associations, CMS released the Proposed Rule for the PFS covering 2021 (hereafter the "Proposed Rule"). The

Proposed Rule initially identified a potentially favorable rate for AECGs based upon a different medical device used as a proxy, but made clear that the data submitted by iRhythm and the industry was insufficient to establish national pricing. To establish national pricing, the Proposed Rule indicated that CMS would require actual invoices to substantiate rates representative of commercial pricing.

6. Like all federal rulemaking, CMS' Proposed Rule was subject to a notice and comment period. During that period, on October 5, 2020, a highly respected consultancy, Muller Consulting & Data Analytics, LLC ("MCDA") submitted as a comment a comprehensive and devastating report about the reimbursement rates identified in the Proposed Rule for 2021. Among other things, MCDA's report concluded that:

- The actual direct costs of the proxy device were significantly higher than the Zio XT, and the proxy device was far more complex and bore no clinical similarity to the Zio XT.
- An examination of an actual invoice from a direct competitor of iRhythm's demonstrated that the actual cost of the Zio XT ranged between $58.78 and $68.22.
- The actual reimbursement rates for the Zio XT based on CMS' standard cost methodology ranged between $75.26 and $85.85 because iRhythm improperly included prohibited, indirect costs for Selling, General and Administrative ("SG&A") expenses and Research and Development ("R&D") expenses to support the inflated reimbursement rates.
- Adoption of the proposed rate would have very serious, negative real-world consequences for taxpayers because in addition to $10.6 million for reimbursable direct costs, the proposed rate would subsidize an additional $32.5 million for unreimbursable SG&A expenses and $6.8 million for unreimbursable R&D expenses.
- A senior executive at another AECG device manufacturer told MCDA that industry participants had no incentive to provide an actual invoice because the actual cost of AECG devices were trending downwards.

7. A well-qualified expert on Medicare reimbursement rates, CPT codes, auditing and compliance retained by Lead Plaintiff, Dr. Freeman, corroborated these findings. Dr. Freeman is a member of the American Medical Association's ("AMA") CPT Advisory Committee. Specifically, as set forth in ¶¶121-33 below, Dr. Freeman affirms that the invoice from iRhythm's direct competitor demonstrates that the rate in the Proposed Rule was significantly inflated, and

that the other medical device used as a proxy had significantly higher actual direct costs and lacked clinical similarity to the Zio XT.

8. Instead of coming clean with investors about threats to Zio XT pricing, between August 2020 and December 2020, iRhythm's then Chief Executive Office ("CEO") Kevin M. King ("King") falsely told investors that the Company had submitted "invoices" to support the reimbursement rates, that CMS "ha[s] everything they can get from us," that the Company's engagement with CMS was "so thorough and so complete," and that the Company had "provided all of the necessary information and feedback" to CMS.

9. On December 1, 2020, CMS released a Final Rule for the PFS (hereafter the "Final Rule") rejecting the high initial proposed rate because of the risks that were known to Defendants. Specifically, the Final Rule concluded that "we are unable to identify accurate national pricing" "given the conflicting information and assertions provided by commenters." It also decided against using the irrelevant proxy price, emphasized the need to see an actual invoice to set commercial pricing, and delegated the decision to set reimbursement rates back to Novitas.

10. On this news, iRhythm's stock price declined by over 20% from its previous day closing price of $240.64 to close at $192.21 on December 2, 2020. The Company's stock price declined again on December 3, 2020 to close at $184.50, and again declined on December 4, 2020 to close at $180.80.

11. On December 2, 2020, King held another conference call with investors to address the Final Rule, and made even more brazenly false statements in response to pointed analyst questions. King falsely minimized the setback by claiming that "this is not a rate cut," blamed the agency's well-established cost methodology as a "rigid framework" that required "invoices" for categories that do not exist, and referred to non-existent "new data" that the Company would use to "shoot[]" for an even higher reimbursement rate. King further misrepresented that there would be absolutely no impact on the rates set by iRhythm's commercial payors if the Medicare rate was reduced. Within two weeks of making these additional statements that misled investors, King resigned from his position as CEO and was replaced by Defendant Michael Coyle ("Coyle").

12. On January 29, 2021, Novitas set reimbursement rates for the Zio XT that reduced the previous rate of $311 set by the MAC down to an average rate within the range of $73.82 and $89.36.

13. Upon the announcement of Novitas' massive rate cut for the Zio XT, the Company's stock price declined by nearly 33% to close at $168.42 on January 29, 2021 from its previous day closing price of $251 on January 28, 2021, on heavy trading volume.

14. Between January 2021 and April 2021, the Company and its competitors met with both Novitas and CMS numerous times in an effort to convince them to raise reimbursement rates. According to evidence that emerged in litigation between one of iRhythm's direct competitors and its acquirer, high level executives believed that the industry had only one opportunity to convince Novitas to set higher rates in early 2021. That same litigation—which consists of a trial record of 824 exhibits, live testimony from numerous fact and expert witnesses, and deposition testimony of 18 witnesses—revealed additional evidence to support a strong inference of scienter in this case, including the following:

- The Chief Financial Officer ("CFO") of one of iRhythm's direct competitors, represented by the same law firm that represents iRhythm in this Action, admitted under oath that the cost of the device—the largest component of total direct costs—was trending downwards, demonstrating that industry participants had no incentive to provide CMS the requested invoice because doing so would justify rather than undermine a rate cut.

- Industry participants were on notice in late 2020 that Novitas' initial high rates were at serious risk.

- Expert analysis and testimony confirmed that iRhythm would lose up to 60% of its current revenue in the absence of a rate increase and run out of cash to sustain its operations in a very short amount of time.

15. Between January 2021 and April 2021, Coyle provided investors with a series of excuses designed to deflect attention from the Company's repeated failure to provide a proper invoice that supported the Zio XT's costs. Coyle repeatedly claimed that the clinical superiority of AECG devices, including an "advanced analytic platform" with "machine learned algorithms," the time spent by a cardiac technician to analyze the scanned information from the Zio XT, the fully integrated nature of the Company's business model, and other administrative costs, substantiated

inflated reimbursement rates. None of this was true. Coyle was on notice of the fact that similar arguments were made by similar providers and CMS rejected them over a decade ago. Coyle also failed to disclose that the largest cost component of the CPT codes, the Zio XT device itself, was trending downwards, and did not admit to investors that iRhythm sought to shift prohibited indirect costs for SG&A expenses and R&D expenses to taxpayers, in direct violation of federal regulations.

16. On April 10, 2021, Novitas further refined its rates in response to the intense lobbying, rejecting the inflated rates urged by iRhythm and its peers but modestly raising the reimbursement rate for the Zio XT to approximately $115, a figure that was still over 60% less than what iRhythm reaped before the Class Period.

17. On this news, the price of the Company's stock again plunged by over 39% to close at $80.36 on April 12, 2021 from its previous day closing price of $132.76 on April 9, 2021.

18. On June 1, 2021, after less than five months of service, Coyle abruptly resigned from his position as CEO and the Company's Board of Directors. Defendant Douglas Devine, ("Devine"), who then served as the Company's CFO, replaced Coyle as the Company's interim CEO. Devine continued to make similar misrepresentations in his short stint at the Company before this Complaint was filed.

19. On this news, the Company's stock price declined by nearly 18% to close at $62.77 on June 2, 2021 from its previous day closing price of $76.25 on June 1, 2021.

20. On July 13, 2021, CMS released the proposed rule that includes updated payment policies, payment rates, and other provisions effective January 1, 2022. In this new proposed rule, CMS explicitly stated that "we remain concerned that we continue to hear that the supply costs as initially considered in our CY 2021 PFS proposal are much higher than they should be." External Extended ECG Monitoring (CPT Codes 93241, 93242, 93243, 93244, 93245, 93246, 93247, and 93248), 86 Fed. Reg. 39178-79 (July 23, 2021). It again emphasized that relevant information such as actual invoices, a more appropriate proxy input or other pertinent information "would be ideal for us to use in establishing fair and stable pricing for these services." *Id.* It yet again stressed that "in the absence of such additional and actionable information (***that is, information that provides***

further context to information that has already been considered) we are proposing to maintain contractor pricing for these services." *Id.* (Emphasis added).

21. In reaction to this final disclosure, which confirmed that iRhythm had not provided the information it claimed it had provided to CMS during the Class Period, on July 14, 2021, the price of the Company's common stock declined by nearly 9% to close at $53.90 from its previous day closing price of $59.07, on heavy trading volume.

22. As a result of Defendants' wrongful acts and omissions, and the resulting precipitous decline in the market value of the Company's securities, Lead Plaintiff and other Class members have suffered significant losses and damages.

JURISDICTION AND VENUE

23. The claims asserted herein arise under Sections 10(b) and 20(a) of the Exchange Act (15 U.S.C. §§ 78j(b) and 78t(a)) and SEC Rule 10b-5 promulgated thereunder (17 C.F.R. § 240.10b-5).

24. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1337 and Section 27 of the Exchange Act (15 U.S.C. § 78aa).

25. Venue is proper in this District pursuant to § 27 of the Exchange Act, 15 U.S.C. § 78aa and 28 U.S.C. § 1931(b). The Company has its principal place of business in San Francisco, California, and the other Defendants reside in this District. Many of the acts and transactions that constitute the alleged violations of the law, including the dissemination to the public of materially false and misleading statements of fact, also occurred in this District.

26. In connection with the acts, conduct and other wrongs alleged in this Complaint, Defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including but not limited to, the United States mail, interstate telephone communications and the facilities of a national securities exchange.

PARTIES

27. During the Class Period, Lead Plaintiff suffered an estimated loss of $1.809 million in reliance on Defendants' misleading statements. ECF No. 22-3 at 2. Lead Plaintiff was damaged

upon the disclosure and/or materialization of the risks concealed by Defendants' Class Period misrepresentations and omissions.

28. Defendant iRhythm is incorporated under the laws of the State of Delaware, with its principal place of business located in San Francisco. iRhythm's common stock trades on the NASDAQ under the ticker symbol "IRTC."

29. Defendant King officially served as the CEO of the Company from July 2012 until January 12, 2021. On December 14, 2020, iRhythm abruptly announced that King would retire as the Company's CEO in January 2021. This abrupt resignation came less than two weeks after CMS announced, on December 1, 2020, its Final Rule on payment policies, payment rates and other services furnished under the PFS on or after January 1, 2021. King made the misleading statements in response to analyst questions identified in Paragraphs 147 through 167.

30. Defendant Coyle became the CEO of the Company on January 12, 2021. On June 1, 2021, Coyle abruptly and unexpectedly resigned from his position as CEO and a member of the Company's Board of Directors. Coyle made the misleading statements in response to analyst questions identified in Paragraphs 168 through 174, and signed the Annual Report that was filed with the SEC and contained the misleading statements identified in Paragraph 170.

31. Defendant Devine served as the Company's CFO from June 2020 to June 2021. On June 1, 2021, Devine began to serve as iRhythm's interim CEO. Devine made the misleading statements in response to analyst questions identified in Paragraphs 175 through 178, and signed the Annual Report that was filed with the SEC and contained the misleading statements identified in Paragraph 170.

32. The Defendants referenced above in ¶29 through ¶31 are sometimes referred to herein collectively as the "Individual Defendants."

33. The Individual Defendants possessed the power and authority to control the contents of iRhythm's SEC filings, press releases, and other market communications. The Individual Defendants were provided with copies of the Company's SEC filings and other communications alleged herein to be misleading prior to, or shortly after, their issuance and had the ability and opportunity to prevent their issuance or cause them to be corrected. Because of their positions with

the Company, and their access to material information available to them but not to the public, the Individual Defendants knew that the adverse facts specified herein had not been disclosed to and were being concealed from the public, and that the positive representations being made were then materially false and misleading. The Individual Defendants are liable for the false and misleading statements and omissions pleaded herein.

SUBSTANTIVE ALLEGATIONS

A. Background

1. iRhythm and its Core Product

34. iRhythm is a digital healthcare company that focuses on AECG devices that seek to diagnose cardiac arrhythmias. The Company went public in 2006 and began commercial operations in 2009 after receiving clearance from the United States Food and Drug Administration ("FDA").

35. Unlike a conventional electrocardiogram ("ECG") test that connects wires to a recording device and provides monitoring between 24 to 48 hours, an AECG attaches to the body and records up to 14 days of electrocardiographic data. AECGs are used to detect heart arrhythmias—abnormal rhythms that cause the heart to beat too fast, too slow, or irregularly. Some heart arrhythmias are harmless while others can cause serious complications such as a stroke.

36. The Zio XT is iRhythm's core product, and accounts for at least 85% of its total revenue. It is a water-resistant, wearable patch-based biosensor combined with a monitor that is attached to a patient's chest and records a patient's heart rhythm continuously for up to 14 days.

37. At the end of up to 14 days of continuous monitoring, the patient mails the Zio XT to iRhythm's Independent Diagnostic and Testing Facility ("IDTF"), where a cardiac technician scans the data and generates a report using iRhythm's proprietary software. Physicians are then provided with the cardiac technician's report and utilize the report to diagnose the patient's condition.

38. The Zio XT has several drawbacks. It does not transmit data in real-time, and there is a large lag between the time that monitoring begins and the time the data is ultimately provided to a physician for a diagnosis. Further, because many hospitals already employ their own ECG

technicians, they are disincentivized from prescribing iRhythm's Zio XT, which requires them to unnecessarily pay for iRhythm's cardiac technicians to review data first.

39. The Zio XT is a fairly basic medical device that consists of a biosensor that detects cardiac rhythm, a memory card, and a patch to affix the device onto the patient's chest.

2. iRhythm's Precarious Revenue Strategy

40. Despite these drawbacks, since receiving clearance from the FDA in 2009, the Zio XT gained a foothold in the AECG market, in part because it was one of the first extended wear monitoring devices on the market.

41. In those early days, because iRhythm was the only manufacturer offering an extended-wear ECG monitoring device, it could essentially name its own price in negotiations with third parties, leading to excessively high reimbursement payments from both Medicare and third-party commercial payers. This is no longer the case, as other manufacturers now offer similar devices.

42. iRhythm's only other product of any significance is the Zio AT patch that the Company began to develop in the middle of 2017. The Zio AT is an external extended-wear ECG monitoring device that purports to provide real-time monitoring and transmittal of data, as opposed to the delayed monitoring services that the Zio XT provides. The Zio AT, however, has failed to establish a foothold in the market and accounts for only 10% of iRhythm's revenues. As a result, iRhythm remains almost exclusively dependent on reimbursement rates and resulting revenues generated by the Zio XT.

43. Indeed, nearly all of iRhythm's revenue is derived from the Zio XT, and the vast majority of the revenue is not through the sale of the device to physicians and hospitals, but by seeking reimbursement from third party payors for scanning analysis and reporting performed by cardiac technicians at its IDTF in Houston, Texas.

44. Direct reimbursement from Medicare related services accounts for approximately 25% of iRhythm's revenue. The rest of iRhythm's revenue comes from commercial contracts with third-party payors. These third-party payors, however, take their cues from the Medicare reimbursement rates, and any change in the Medicare reimbursement rates generally impacts the

price paid by commercial payors. This impact is not immediate because parties are bound by existing contracts but will inevitably materialize when commercial contracts are renewed.

3. iRhythm's Early Success Invites Competition

45. The high reimbursement rates from Novitas, combined with the simplicity of the Zio XT itself, invited competition, as several competitors moved to exploit the AECG market.

46. The AECG market came to be dominated by iRhythm, Bardy, BioTelemetry, Inc. ("BioTelemetry") and Preventice Solutions Inc. ("Preventice"). iRhythm's competitors were quick to make improvements to the weaknesses of the Zio XT by adopting better patch placement, increasing the number of sensors, reducing the time-to-reporting, and increasing rhythm-recording clarity. Very quickly, the Zio XT began to lose its edge to newer and more advanced AECG devices.

47. Indeed, as early as 2018, scientific journals compared the Zio XT to devices produced by the Company's competitors, including Bardy's Carnation Ambulatory Monitor ("CAM"), and found that the CAM patch "identified significantly more arrhythmias and resulted in better, more informed clinical decision-making" than the Zio XT. *See* Robert Rho, Mark Vossler, Susan Blancher, & Jeanne E. Poole, *Comparison of 2 Ambulatory Patch ECG Monitors: The Benefit of the P-Wave and Signal Clarity*, 203 Am. Heart J. 109 (2018).

48. Criticism was not limited to outside of the industry, but also levied by iRhythm's own competitors and former employees:

- "We have the best algorithm in the business… some of the buzz words that get investors excited don't matter to physicians… everyone has automation on the backend." – Current senior executive at a large extended wear ECG monitoring company.

- "[Major product] has never been compared to another patch to measure performance, and that is intentional by [major provider] because it is the same thing for all the patches. They only show diagnostic yield relative to a standard Holter to compare performance, which is an easy comp." – Current senior executive at a large extended wear ECG monitoring company.

- "iRhythm benefitted from being the only player in the space for a long time… now you have a whole host of people all at the same time… we're doing it with a more accurate monitor. iRhythm is 'spewing a lot of hot air on these analyst calls.'" –

Current senior employee at a smaller patch competitor who was formerly an employee of iRhythm.

- "[The device] was a cool idea, and that device is super easy to copy. [All the companies are] doing the same thing [now]." – Former sales representative at a large extended wear ECG monitoring company.

See October 5, 2020 MCDA Report, pp. 46-48, available at https://www.regulations.gov/comment/CMS-2020-0088-27016.

49. iRhythm's competitors did not just improve upon the technology, but also developed a better business model by manufacturing a diversified product line. BioTelemetry and Preventice predominantly focus on Mobile Continuous Outpatient Telemetry ("MCOT") devices that measure and record heart rhythms between 10 to 30 days, with only 9% and 15% of their annual revenue dependent on AECG devices comparable to the Zio XT. BioTelemetry and Preventice were also recently acquired by international behemoths that provide a much larger financial support structure than iRhythm has. BioTelemetry merged with Koninklijke Philips N.V.—one of the largest multinational conglomerates in the world that focuses on health technology—in February 2021. Similarly, Preventice was acquired by Boston Scientific Corporation in January 2021. Bardy is in the process of merging with Hill-Rom, an established hospital bed and medical device manufacturer based in Chicago, Illinois with billions of dollars in revenue. Hence, iRhythm stands alone as completely exposed to a crippling impact from reimbursement rate cuts for the Zio XT.

B. The Regulatory Landscape for Reimbursement Rates

50. Medicare is administered by the Department of Health and Human Services through the CMS and its contractors. CMS and its contractors pay for outpatient medical services according to the PFS. One of the principal aims of CMS when it sets rates is to lower the costs of healthcare. Each calendar year, the CMS releases a proposed rule that updates payment policies, payment rates and other provisions for services provided under the Medicare PFS that applies to the following calendar year.

51. Medicare sets rates for reimbursement of medical devices and related services through CPT codes. CMS, as an arm of the Department of Health and Human Services, creates

and administers the reimbursement policy for Medicare, and oversees adoption and pricing of CPT codes for medical services. Commercial payers usually pay reimbursement rates that are one and a half times to two times the amount set by CMS for the CPT codes.

52. New services that are based on novel technologies are assigned Temporary Category III CPT codes, and CMS typically delegates pricing authority to local MACs, which are private organizations within designated regions that are authorized by CMS to set pricing for Category III CPT codes.

53. After iRhythm received FDA approval for the Zio XT in 2009, the Company applied for a set of Category III CPT codes, for which it received approval in 2011, with an implementation date of January 2012.

54. Category III CPT codes are not based on an intense evaluation process to determine reimbursement rates unlike permanent Category I codes, but instead are "contractor priced," which means that their reimbursement rate is established by each of the MACs in their respective regions.

55. Industry participants typically work with the CPT Editorial Panel of the AMA to lobby CMS for permanent Category I codes and help establish that a service constitutes "standard of care" for the purposes of reimbursement. The AMA's Resource-Based Relative Value Scale Update Committee (hereafter the "RUC") recommends the adoption of Category I codes and related pricing to CMS. While CMS gives weight to the RUC's input and recommendations, it is not obligated to accept the RUC's recommendation in the final rule, and it can modify pricing based on its own analysis or delegate pricing to MACs in the final rule. Indeed, it is beyond dispute that CMS' process for developing rates is "iterative," and builds upon input from all participants, including those who submit information in the notice-and-comment period.

56. iRhythm only needed to secure a favorable rate from one MAC and then leverage that rate to seek higher reimbursement from third-party commercial payors. iRhythm was able to secure that favorable reimbursement rate from Novitas Solutions, which administered Region JH for CMS, and agreed to a $316 allowable fee (later adjusted to $311) for the Zio XT. iRhythm subsequently set up an IDTF in Houston, over which Novitas presides, and leveraged its Novitas rate to obtain high rates from commercial payers.

57. Notably, the reimbursement rates set by Novitas before the Class Period began were significantly outside the norm of rates set by other MACs for ECG monitoring devices. In fact, Novitas' rates were 6.5 times higher than the median reimbursement rate set by other MACs in other jurisdictions.

58. Under the Administrative Procedures Act, federal agencies are required to provide notice of proposed rules that are published in the Federal Register, and interested parties are usually required to be given the opportunity to participate in the rule-making process by submitting data, arguments, or other information. A proposed rule can thus be modified in light of public comment, so long as the final rule promulgated by the agency is a natural outgrowth of the substance of the proposed rule. A final rule is considered a logical outgrowth of a proposed rule when parties should have anticipated that a change was possible based on the information received during the notice-and-comment period between the proposed rule and the final rule.

59. Federal law does not require agencies to finalize any proposed rule. Instead, "[a]gencies are free—***indeed, they are encouraged***—to modify proposed rules as a result of the comments they receive." *Ne. Maryland Waste Disposal Auth. v. E.P.A.*, 358 F.3d 936, 951 (D.C. Cir. 2004) (emphasis added). The notice-and-comment period ensures that an agency's rules are tested with diverse public comments, and any affected party is allowed an opportunity to develop evidence to support its objections and thereby improve the final rule promulgated. Comments received by a federal agency are, in fact, expected to affect the outcome of a final rule.

C. The Proposed Rule for 2021

60. On August 3, 2020, CMS released the Proposed Rule for the Medicare PFS applicable on or after January 1, 2021. *See* External Extended ECG Monitoring (CPT Codes 93224, 93225, 93226, 93227, 93XX0, 93XX1, 93XX2, 93XX3, 93XX4, 93XX5, 93XX6, and 93XX7), 85 Fed. Reg. 50164 (Aug. 17, 2020). The Proposed Rule was followed by a several monthslong notice-and-comment period that was expected to culminate in the release of the Final Rule at the end of the year. The Proposed Rule identified two new Category I codes related to AECG devices. Category I CPT codes 93XX0-93XX7 were expected to replace Category III CPT codes 0295T-0298T.

61. Based on the RUC's recommendation, CMS proposed reimbursement rates of $375.83 for CPT code 93XX2 and $386.16 for CPT code 93XX6. However, neither the RUC nor CMS received an actual invoice from iRhythm or any other industry participant that substantiated claims that the device actually cost hundreds of dollars. Without such information, the RUC resorted to the weighted mean of actual payment that iRhythm received from claims submitted to insurers to seek reimbursement for the device. However, in the Proposed Rule, CMS acknowledged that it received certain insurer claims data, but emphasized that "we cannot establish supply pricing based on an analysis of claims data in absence of a representative invoice." *Id*. at 50165. For this reason, CMS proposed to use a "crosswalk," whereby an existing device is used to supply a "proxy price." The device that the CMS considered for a "crosswalk" was an externally programmable implanted sacral neurostimulator, a device implanted inside the body and used to treat and improve urinary and fecal continence. While CMS acknowledged in the Proposed Rule that the neurostimulator was not clinically similar to AECG devices, CMS noted that it was "the closest match from a pricing perspective to employ as a proxy ***until we are able to arrive at an invoice*** that is representative of commercial market pricing." *Id*. at 50166 (emphasis added).

D. The October 5, 2020 MCDA Report

62. MCDA is a consulting firm based in Washington, D.C that was founded by Mr. James Muller, and specializes in U.S. healthcare policy and data research. Mr. Muller has 13 years of experience in healthcare reimbursement policy, quality measurement, patient clinical profiling and analysis, and modeling of current healthcare affairs. His experience includes replicating and modeling the PFS Practice Expense ("PE") rate-setting methodology. The PE component is composed of the resources involved in furnishing medical services. Lead Plaintiff consulted with Mr. Muller in connection with the claims asserted in this Action.

63. On October 5, 2020, MCDA submitted a detailed 89-page report to CMS that opposed the proposed payment reimbursement rates for CPT codes 93XX2—which are for devices that last between 48 hours and 7 days—and 93XX6—which are for devices that last between 7 days and 15 days. MCDA's report was submitted to CMS in the notice-and-comment period

between the announcement of CMS' Proposed Rule in August 2020 and CMS' Final Rule in December 2020.

64. MCDA argued that the Proposed Rule's preliminary rates for the CPT codes associated with the Zio XT were four times higher than permitted under CMS' standard PE cost accounting methodology. CMS' standard PE cost methodology establishes payment rates for services based on a bottom-up analysis of the direct costs of providing a service but standardizes and limits reimbursement for indirect costs such as marketing and promotion, research and development, software development, and other corporate overhead (hereafter the specific direct costs and the standardized, limited indirect allowance are called "PE rates").

65. According to MCDA, CMS calculates the PE rates primarily by identifying the "direct costs" of a device/service, which are the costs and labor employed to manufacture the product. CMS does not, however, allow companies to include individual "indirect costs" such as sales and marketing expenses. Instead, it only allows a standardized allowance for indirect costs, which is otherwise known as the "indirect allocator." Importantly, the indirect allocator standardizes the amount a company can receive in indirect costs through a metric based on the historical surveyed ratios of indirect-to-direct costs, clinical labor costs, and work performed by physicians, and does not allow companies to simply include all indirect costs, as that would incentivize companies to incur unnecessary indirect costs and inflate their reimbursement rates.

66. MCDA analyzed the costs identified in iRhythm's financial statements to determine the amount of iRhythm's indirect costs, to ascertain whether such costs were impermissibly being included in the proposed reimbursement rates. It then subtracted the inappropriate indirect costs to calculate the actual direct costs of the Zio XT patch. According to MCDA, these calculations showed that the proposed reimbursement rates for the Zio XT were grossly inflated.

67. iRhythm could not get away with such inflation if it submitted traditional invoice data to CMS like most companies, because such invoices would allow CMS to clearly identify the direct cost of each component in a device or service. To obscure the truth, iRhythm declined to submit actual invoices, instead providing CMS with insurance claim and cost data that showed only the total cost charged to third party payors without any breakdown of the cost of the different

components of the Zio XT. According to MCDA, this was improper because it concealed required information about the actual direct input costs for the Zio XT. *See* October 5, 2020 MCDA Report, p. 3.

68. MCDA then analyzed invoice data from iRhythm's competitors to calculate the true direct costs of the Zio XT that iRhythm should have, but did not, identify by providing its own invoices to CMS. MCDA also reviewed interviews with executives at iRhythm's competitors, who stated that the true cost of the Zio XT was dramatically less than the reimbursement rates in the Proposed Rule, and Defendants knew this fact, which is why they chose not to provide CMS with any traditional invoice data. MCDA further reviewed the analysis of a well-qualified Robotics Engineer, who was also a user of the Zio XT, and the Robotics Engineer confirmed that the actual cost of the Zio XT was far lower than the rates identified in the Proposed Rule. Finally, MCDA outlined the economic distortions and adverse consequences that would result if CMS finalized the rates of $375.83 for 93XX2 and $386.16 for 93XX6.

69. Ultimately, MCDA concluded that the actual PE rates should be approximately $66.25 for CPT code 93XX2 and $82.66 for CPT code 93XX6, compared to the Proposed Rule's rates of $375.83 for CPT code 93XX2 and $386.16 for CPT code 93XX6.

1. Analysis of Proxy Items

70. MCDA first analyzed the Proposed Rule's use of a "proxy" input—the externally programmable implanted neurostimulator—and concluded that the proxy input lacked clinical and technical relevance to extended wear AECG devices like Zio XT. MCDA noted that the proxy input was chosen solely because it was the closest supply item in price ($416.85 total cost per service compared to iRhythm's claim that its services involving Zio XT cost $413.24).

71. MCDA identified the disparities between the proxy input and AECG devices. Neurostimulators are highly complex FDA approved devices implanted into the body with high powered batteries that can last for five to seven years and can be controlled wirelessly with a smartphone. In contrast, the Zio XT is not approved for implantation into the body, lasts for only 14 days, and will not interface with a smartphone.

72. Moreover, the neurostimulator is far more complex than an AECG device because it is a medical treatment, not just a diagnostic tool. The Zio XT is a basic electrode and printed circuit board enclosed by plastic that collects and stores a small amount of data to be downloaded at a later date and lasts for only 14 days. In contrast, the neurostimulator is a complex wireless device planted inside the body with an operating system that, instead of simply observing and storing data, acts on the body by applying a controlled electric current to the sacral nerve to improve urinary and fecal continence.

73. Accordingly, MCDA found that the proxy input served as a grossly inappropriate comparator for the Zio XT.

2. Direct Cost of the Zio XT Patch

74. In challenging the Proposed Rule's rates for the Zio XT, MCDA first examined how CMS calculates reimbursement rates. Specifically, MCDA analyzed previous rulings by CMS and found that the standard CMS methodological principles relevant to the valuation of actual costs are:

- Indirect costs incurred by the provider billing the service are not included as direct inputs.
- A direct input must be exclusively used for one service at one time. If an input into a service can be used for multiple services simultaneously, then it is an indirect cost that cannot be included.
- If a direct input into a service can be used in multiple services (but exclusively for one at a time), then that input is a direct equipment input.

75. MCDA calculated the "true" direct cost of the Zio XT by identifying the overall costs to furnish the Zio XT—the total operating expenses—and then subtracted inappropriate indirect costs, such as R&D costs and SG&A costs. Throughout its calculations, MCDA used iRhythm's 2019 10-K to identify the actual "direct costs" for the Zio XT based on the Company's "cost of revenue," as well as indirect costs such as R&D costs and SG&A costs.

76. MCDA pointed out that, by iRhythm's own admission in its 2019 10-K filing, the Company's "cost of revenue" included prohibited indirect costs such as equipment and infrastructure expenses, and amortization of internal-use software. As a result, while MCDA

attempted to remove all prohibited indirect costs from the total direct cost figure, it was unable to do so, making MCDA's calculations likely higher than the true total direct cost of the Zio XT.

77. However, when MCDA subtracted the Company's SG&A costs and R&D costs, it was able to determine that the actual direct cost of the Zio XT patch was $41.17 per service.

78. MCDA also put together a table to outline these direct cost calculations:

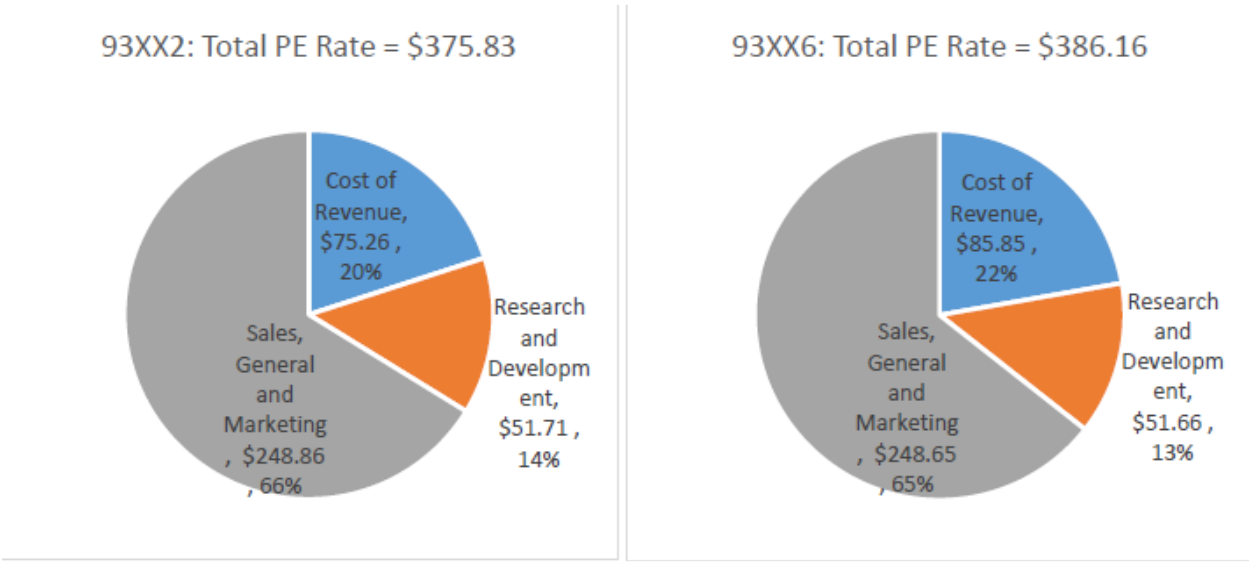
			Other Directs to Exclude			Est Cost per Service net of Other Directs	Adjustment to Align with Proxy Code	Patch Supply Input		
Cost Category	Total Costs (10-K 2019 Costs)	Est. Cost per Service	93XX2	93XX6	50/50 Blend			Incl All Costs	Excl Sales, General & Administrative	Excl R&D
Cost of Revenue	$ 52,485,000	$ 90.85	$ 43.91	$ 54.73	$ 49.32	$ 41.53	0.99134	$ 41.17	$ 41.17	$ 41.17
Research & Development	$ 37,299,000	$ 64.56				$ 64.56	0.99134	$ 64.00	$ 64.00	n/a
Sales, General & Administrative	$ 179,523,000	$ 310.75				$ 310.75	0.99134	$ 308.06	n/a	n/a
TOTAL	***$ 269,307,000***	***$ 466.17***				***$ 416.85***	***0.99134***	***$ 413.24***	***$ 105.18***	***$ 41.17***

79. MCDA then calculated the PE rates for the Zio XT by utilizing CMS' own practice expense rate-setting methodology, but adjusting to remove the SG&A and R&D costs that iRhythm had inappropriately folded into its claimed costs.

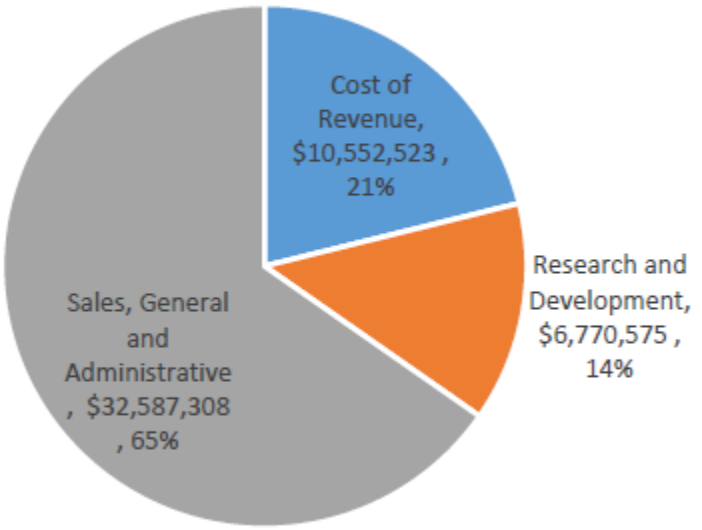
80. Removing the inappropriately-included indirect costs decreased the baseline PE rates to $75.26 for CPT code 93XX2 and $85.85 for CPT code 93XX6:

Scenario	Direct Supply Input Assumption	93XX2 >48 hour - 7 Days		93XX6 >7 - 15 Days	
		PE RVU	PE Rate	PE RVU	PE Rate
CMS Published	$ 413.24	11.65	$ 375.83	11.97	$ 386.16
Baseline - Include all Costs including Sales, General & Administrative and R&D	$ 413.24	11.65	$ 375.83	11.97	$ 386.16
Include Cost of Revenue and Research & Development	$ 105.18	3.94	$ 126.97	4.26	$ 137.51
Include only Cost of Revenue	$ 41.17	2.33	$ 75.26	2.66	$ 85.85

81. As a result, MCDA found that, under the proposed reimbursement rates, only 20% of CPT code 93XX2's proposed rate and 22% of CPT code 93XX6's proposed rate was attributable to the actual cost of revenue, while the rest simply represented prohibited indirect costs:



82. These inflated rates would have very serious, negative real-world consequences for taxpayers. According to MCDA, implementation of the inflated reimbursement rates would mean that Medicare would pay iRhythm approximately $49.9 million, only $10.6 million of which actually amounted to reimbursable direct costs of the Zio XT, and the rest impermissibly subsidized SG&A expenses ($32.5 million) and R&D expenses ($6.8 million):



83. MCDA also reviewed analysis by a well-qualified Robotics Engineer, who examined iRhythm's patents to estimate the cost of the Zio XT. The Robotics Engineer had over 30 years of experience in the design, production, procurement, and management of subcontractors utilizing Printed Circuit Board Assemblies ("PCBAs")—the primary electronic component of the Zio XT patch. Additionally, the engineer was a past user of the Zio XT himself and was therefore familiar with the device as a consumer.

84. The Robotics Engineer estimated that the Bill of Materials to produce each PCBA when produced in bulk volume was "most likely no more than $30-40, and was extremely unlikely to be higher than $50 per unit[.]" *See* October 5, 2020 MCDA Report, p. 24. The Robotics Engineer's estimate acknowledged that there may be additional costs associated with shipping and refurbishing the product, but that those costs were unlikely to be more than $30-40.

85. After fully analyzing the Zio XT, the Robotics Engineer concluded that "[e]ven if there was significant undercounting of cost drivers … the cost to manufacture the most expensive physical component of the Zio XT device is relatively low." *Id.*

86. Ultimately, the Robotics Engineer concluded that, if each PCBA were used only once, the total cost per unit—including shipping and refurbishing—would be no more than $80-

90. Because, however, the PCBAs are designed to be re-used multiple times, the $80-90 cost would decrease further over time.

3. Comparison with Similar Devices

87. MCDA also reviewed comparable AECG devices and their invoices to calculate comparable PE rates. Critically, MCDA compared the efficacy of the comparable devices to the Zio XT to demonstrate that they were comparable devices. For example, MCDA compared the Zio XT to BioTelemetry's ePatch 2.0 because it was the second largest biller to Medicare, after the Zio XT. As the following table illustrates, the ePatch has all of the features of the Zio XT (and then some):

	ePatch™	Zio® XT[1]
Extended Holter	✓	✓
Comprehensive Product Portfolio	✓	
Record Up to 14 Days	✓	✓
Channels	Single or 3-Channel	Single only
If Patch Peels Off	Reapply Fresh Patch	Service Ends
Number of Replacement Patches Included	Up to 2	
Alternate Non-patch Option* (ePatch sensor with lead wire adapter)	✓	
Mail-Back Option	✓	
In-office Uploads**	✓	

88. However, actual invoice data from BioTelemetry indicates a reimbursement rate much lower than that proposed initially for Zio XT. Applying the standard methodology for calculating reimbursement rates to this data, MCDA arrived at a PE rate for CPT code 93XX2 that ranged between $58.78 to $68.22, and a PE rate for CPT code 93XX6 that ranged between $69.60 to $85.21.

89. MCDA repeated this process to compare the Zio XT to two other ECG monitoring devices: ScottCare's novi+ and Cardiac Insight's Cardea SOLO System. With ScottCare's novi+, MCDA reviewed a purchase invoice and a contract to calculate its PE rates. MCDA was unable to

obtain a quote or purchase invoice for Cardiac Insight's Cardea SOLO System, and instead used the GSA Advantage website's list of product pages, along with Cardiac Insight's own published financial case studies to calculate the appropriate PE rates.

90. Using the same analysis, MCDA found that, ScottCare's novi+ PE rates for CPT code 93XX2 ranged from $80.91 to $87.43, and for CPT code 93XX6 ranged from $111.00 to $119.44. For Cardiac Insight's Cardea SOLO System, MCDA arrived at a PE rate for CPT code 93XX2 that ranged between $163.30 to $177.12. MCDA took care to note that Cardea SOLO patches attained the highest PE rate because—unlike the other ECG monitoring devices, including iRhythm's Zio XT — "Cardiac Insight chooses to sell their patches as a one-use disposable supply and not re-use them across multiple services." *See* October 5, 2020 MCDA Report, at p. 6.

91. The following table provides a full breakdown of direct costs and PE rates based on quotes and purchase invoices for the comparable ECG monitoring devices:

	93XX2 (>48 hours to 7 days)			*93XX6 (>7 days to 15 days)*		
	Total Direct Costs	PE RVU	PE Rate	Total Direct Costs	PE RVU	PE Rate
Current CMS Proposal	***$457.15***	***11.65***	***$ 375.83***	***$467.97***	***11.97***	***$ 386.16***
BioTelemetry ePatch®						
ePatch® 3-year Useful Life / Software Low Tier / Software 2-Year Useful Life	$ 72.63	2.02	$ 65.20	$ 92.56	2.52	$ 81.30
ePatch® 3-year Useful Life / Software Mid Tier / Software 2-Year Useful Life	$ 73.93	2.05	$ 66.25	$ 94.25	2.56	$ 82.66
ePatch® 3-year Useful Life / Software High Tier / Software 2-Year Useful Life	$ 76.37	2.11	$ 68.22	$ 97.40	2.64	$ 85.21
ePatch® 5-year Useful Life / Software Low Tier / Software 2-Year Useful Life	$ 66.70	1.87	$ 60.41	$ 80.69	2.22	$ 71.71
ePatch® 5-year Useful Life / Software Mid Tier / Software 2-Year Useful Life	$ 68.00	1.91	$ 61.46	$ 82.38	2.27	$ 73.08
ePatch® 5-year Useful Life / Software High Tier / Software 2-Year Useful Life	$ 70.44	1.97	$ 63.43	$ 85.53	2.34	$ 75.62
ePatch® 3-year Useful Life / Software Low Tier / Software 5-Year Useful Life	$ 70.61	1.97	$ 63.57	$ 89.95	2.45	$ 79.19
ePatch® 3-year Useful Life / Software Mid Tier / Software 5-Year Useful Life	$ 71.25	1.99	$ 64.09	$ 90.78	2.48	$ 79.86
ePatch® 3-year Useful Life / Software High Tier / Software 5-Year Useful Life	$ 72.44	2.02	$ 65.05	$ 92.32	2.51	$ 81.11
ePatch® 5-year Useful Life / Software Low Tier / Software 5-Year Useful Life	$ 64.68	1.82	$ 58.78	$ 78.08	2.16	$ 69.60
ePatch® 5-year Useful Life / Software Mid Tier / Software 5-Year Useful Life	$ 65.32	1.84	$ 59.30	$ 78.91	2.18	$ 70.27
ePatch® 5-year Useful Life / Software High Tier / Software 5-Year Useful Life	$ 66.51	1.87	$ 60.26	$ 80.45	2.22	$ 71.52
ScottCare® novi+™						
novi+™ 2-Year / Include software as Direct (2-year)	$100.15	2.71	$ 87.43	$139.77	3.70	$ 119.44
novi+™ 2-Year / Include software as Direct (5-year)	$ 96.03	2.61	$ 84.10	$134.44	3.57	$ 115.13
novi+™ 2-Year / Exclude software from Directs	$ 92.08	2.51	$ 80.91	$129.32	3.44	$ 111.00
novi+™ 5-Year / Include software as Direct (2-year)	$ 81.14	2.23	$ 72.07	$101.75	2.75	$ 88.72
novi+™ 5-Year / Include software as Direct (5-year)	$ 77.02	2.13	$ 68.75	$ 96.42	2.62	$ 84.42
novi+™ 5-Year / Exclude software from Directs	$ 73.07	2.03	$ 65.55	$ 91.30	2.49	$ 80.28
Cardea SOLO™						
Cardiac Insight Studies: $147.88 Supply	$191.94	5.01	$ 161.58	na	na	na
GSA Advantage: $167.11	$211.17	5.49	$ 177.12	na	na	na

92. The table illustrates that the PE rates for comparable ECG monitoring devices are consistent with the PE rates of the Zio XT once improper indirect costs are removed from iRhythm's total costs.

4. Statements of Other Parties

93. MCDA was not the only party to take issue with the proposed reimbursement rates, the actual direct costs to produce AECG devices, iRhythm's failure to provide traditional invoice data, or iRhythm's assertions of product superiority.

94. As outlined in MCDA's report to CMS, MCDA reviewed interviews with a current senior executive at a large extended wear ECG monitoring company, who expressed surprise that the Proposed Rule overlooked standard methodology and instead used an irrelevant proxy input that resulted in an inflated reimbursement rate. Significantly, the senior executive did not expect any other ECG monitoring companies to deviate from iRhythm's strategy and actually provide CMS with a traditional invoice because doing so would decrease reimbursement.

95. Another senior executive at one of iRhythm's competitors stated that the production costs for each AECG device was less than $50, and would decrease over time as demand scaled upwards. The senior executive also pointed out that the software utilized by other manufacturers was comparable to iRhythm's. The senior executive emphasized that his company's ECG monitoring device—produced at less than $50 per unit—was superior to the Zio XT, as it allowed customers to own and control the data, as opposed to the Zio XT which requires doctors to request reports after iRhythm's cardiac technicians scan and analyze the data.

5. Economic Distortions and Adverse Consequences

96. After identifying the true direct costs of the Zio XT, MCDA discussed the economic distortions and adverse consequences that would result if CMS finalized the inflated reimbursement rates from the Proposed Rule. Most notably, MCDA delineated how "CMS would be creating a significant economic distortion that can be exploited by providers and suppliers to generate remarkably high profits. [The Proposed Rule] sets up a dangerous environment of perverse economic incentives that can and likely will be exploited – most likely legally – at the detriment of taxpayers, the benefit of physicians and suppliers, and without any clear benefit to patients." *See* October 5, 2020 MCDA Report, p. 42.

97. MCDA reviewed interviews with senior executives at iRhythm's competitors, who stated that the exponential increase in reimbursement rates for the Zio XT would create an incentive for AECG manufacturers to adopt at least four different abusive tactics if adopted in the Final Rule:

a. AECG providers simply generate incremental profits from the inflated reimbursement rates, costing Medicare and taxpayers exponentially more money;

b. Dominant AECG providers like iRhythm spend aggressively on direct-to-consumer sales and marketing to promote products regardless of clinical necessity, thereby generating greater profits at the expense of Medicare and taxpayers;

c. AECG providers spend aggressively on sales and marketing in an effort to induce physicians to prescribe the devices, and then increase the charge to physicians to cover the increased sales and marketing efforts, thereby increasing profits at the expense of Medicare and taxpayers; and

d. AECG providers engage in fraud and abuse by encouraging the use of AECG devices, even without cause or need, to capitalize on the inflated reimbursement rates at the expense of Medicare and taxpayers.

98. Consequently, MCDA urged CMS not to adopt the initially proposed inflated PE rates in the Final Rule.

E. iRhythm Deceives Investors in its Conclusory and Misleading Response to the MCDA Report

99. On October 5, 2020, iRhythm filed a 3-page perfunctory response comment intended to prevent both investors and the CMS from appreciating the facts raised by MCDA in its report. *See* October 5, 2020 iRhythm Comment to CMS, available at https://www.regulations.gov/comment/CMS-2020-0088-30888.

100. iRhythm's October 5, 2020 comment falsely claimed that the Zio XT was entitled to an inflated rate because it provided the benefits of a longer duration of service and analyzed more clinical data than the other devices, including BioTelemetry's ePatch. This claim was false

because the ePatch also provides up to 14 days of continuous monitoring and has virtually the same features as the Zio XT.

101. The October 5, 2020 comment also stressed that the only studies used to craft the recommendations by healthcare experts involved iRhythm's Zio XT, and no other AECG devices. iRhythm argued that this fact, combined with the fact that the Zio XT constituted 97% of all Medicare billing for AECG devices, meant that CMS should disregard the evidence provided by MCDA concerning the actual invoice data of BioTelemetry's ePatch.

102. As a result, iRhythm urged CMS to adopt the inflated reimbursement rate in the Final Rule.

F. The Final Rule for 2021

103. On December 1, 2020, CMS released the Final Rule that established payment policies, payment rates and provisions for AECG monitoring and other medical services for calendar year 2021. In the Final Rule, CMS again emphasized that it did not receive any traditional invoice to support the inflated reimbursement rates initially proposed for AECG devices, and that CMS requires "an invoice representative of commercial market pricing to establish a national price for a new supply or equipment item." External Extended ECG Monitoring (CPT Codes 93224, 93225, 93226, 93227, 93241, 93242, 93243, 93244, 93245, 93246, 93247, and 93248), 85 Fed. Reg. 84632 (Dec. 28, 2020). CMS also stressed that while it was aware of arguments from iRhythm and other manufacturers regarding how data from an AECG device is uploaded for the healthcare provider's use "we cannot establish supply pricing based on an analysis of claims data and in absence of a representative invoice." *Id.* Because Zio XT accounted for the majority of the Medicare-reimbursed market, these statements directly reflected iRhythm's failure to provide required documentation.

104. In the Final Rule, CMS acknowledged the severe criticisms contained in MCDA's October 5, 2020 Report, and found that "[g]iven the conflicting information and assertions provided by commenters, we are unable to identify accurate national pricing" for devices such as the Zio XT. CMS again welcomed the submission of additional invoices or other pricing information to determine accurate pricing for the AECG devices. It also refused to establish pricing based on

using the neurostimulator as a proxy price "pending additional information." *Id.* at 84633-34. While CMS maintained Category I CPT codes for AECG devices, allowing those services to be provided and billed to Medicare patients, it again delegated pricing for those codes to the regional MACs for calendar year 2021. Hence, Novitas remained responsible for determining the reimbursement rates for the Zio XT.

105. On this news, iRhythm's stock price declined by over 20% from its previous day closing price of $240.64 to close at $192.21 on December 2, 2020. The Company's stock price declined again on December 3, 2020 to close at $184.50, and again declined on December 4, 2020 to close at $180.80.

106. Within two weeks of the Final Rule's release, King abruptly retired as the Company's President and CEO. On January 12, 2021, Coyle became the Company's CEO.

G. The December 30, 2020 MCDA Report

107. On December 30, 2020, after CMS delegated the decision to set reimbursement rates back to the MACs for 2021, MCDA circulated another report that directly addressed and refuted the arguments made by iRhythm in its October 5, 2020 comment.

108. MCDA addressed iRhythm's claims that the existing reimbursement methodology was inappropriate for a vertically integrated company like iRhythm, and did not fully consider the alleged high clinical value of the Zio XT. Additionally, MCDA presented an updated simulation of the PFS rates, which it originally produced in the October 5, 2020 Report to establish what the true reimbursement rates should be, recalculated using 2021 PFS Final Rule data and methodology.

1. The Appropriateness of the Standard Methodology

109. With respect to iRhythm's claim that "clinical value" itself justified above-cost reimbursement rates, MCDA emphasized that nothing in the Social Security Act permitted "clinical value" to be taken into account when setting PE rates, which are instead largely based on the actual cost of the device itself plus a standardized amount for indirect costs designed to prevent providers from recouping impermissible costs based on their own subjective opinions.

110. MCDA then rebutted iRhythm's false contention that vertical integration justified high reimbursement rates. MCDA pointed out how, even with data limitations due to vertical

integration, CMS could use invoice data from comparable AECG devices, such as BioTelemetry's ePatch, which were identified and discussed in MCDA's October 5, 2020 Report.

111. MCDA noted that CMS grappled with a similar issue in 2008 concerning direct inputs for vertically integrated providers of cardiac monitoring services, which demonstrated that a manufacturer's claim that accurate invoicing could not be provided because of vertical integration would not prevent CMS from faithfully applying its reimbursement methodology in the Final Rule. The 2008 situation that MCDA referenced involved LifeWatch Services, Inc. ("LifeWatch") and CardioNet, Inc. ("CardioNet"), and is outlined in Section M below. *See* ¶¶179-83. Like iRhythm, LifeWatch and CardioNet argued that the benefits of their 24/7 remote cardiac monitoring services could not be accurately captured due to their unique business structures, and as a result, the PE rates did not reflect their proper relative costs. After careful consideration, CMS rejected these arguments and applied its standard methodology, identifying direct cost inputs despite the manufacturers' claim that vertical integration made such inputs unmeasurable.

112. With respect to iRhythm's claim that high operating costs justified high reimbursement rates, MCDA demonstrated that its actual operating costs attributable to Zio XT were in fact low after stripping out prohibited indirect costs attributable to SG&A and R&D that iRhythm had improperly sought to fold into the reimbursement rate. MCDA also showed that iRhythm's actual direct costs closely match the direct costs of BioTelemetry's ePatch, for which an invoice was available and examined by MCDA.

113. Finally, MCDA directly addressed iRhythm's misleading claim that the cost of specialized analytical software was unaccounted for in the standard reimbursement methodology. MCDA responded that the cost of the software was already accounted for under the standard methodology in other services and could be accounted for in the standard reimbursement methodology for 932X2 and 932X6. As MCDA showed, even if iRhythm declined to provide invoices detailing analytical costs, the direct cost could be derived either by backing out other improperly-included costs like SG&A and R&D, or estimated by reference to comparable costs of the analytical software for BioTelemetry's ePatch, which MCDA estimated was between $3.95 and $9.95 per service. MCDA further highlighted that if iRhythm's purported software and "deep

learning" algorithm related costs were baked into the inflated reimbursement rates from the Proposed Rule, the actual cost of that component would range between $830,000 to $1,070,000 ***in total (not per unit)***. Notably, the highest cost of software in the entire CMS fee schedule, which is for a highly-advanced Electrophysiology, Pulmonary Vein Processing Software that performs full high-resolution 3-D mapping of hearts, allows fly-through exploration of the digital representation of the heart, and automatically identifies and measures the size of different parts of heart is only $109,774 ***in total (not per unit)***.

114. Consequently, in order for iRhythm's specialized analytical software to justify the inflated PE rates of CMS' Proposed Rule, it would need CMS to allow costs more than seven times the highest cost for any software in the entire CMS fee schedule. As a result, MCDA demonstrated that iRhythm's argument that its analytical software justified inflated PE rates was false.

2. MCDA's Rebuttal to iRhythm

115. MCDA also refuted iRhythm's false claim that the BioTelemetry ePatch was a poor comparison to the Zio XT, showing that both the length and the clinical yields of the two devices are likely similar. iRhythm had previously stated falsely that BioTelemetry's ePatch does not provide up to 14 days of monitoring. *See* October 5, 2020 iRhythm Comment to CMS, p. 2.

116. MCDA further observed that the quantity of clinical studies is categorically "irrelevant" to the calculation of direct costs, which requires the best possible ***invoice or cost data*** to make a determination.

117. MCDA also criticized the "running theme through iRhythm's assertions …. that, because they were the only extended external ECG provider who actively participated in the RUC process, and that the RUC therefore used information supplied by iRhythm to review, that CMS should ignore the information for other major products that have validly billed and will continue to validly bill under these codes." *See* December 30, 2020 MCDA Report, at pp. 19-20, available at https://www.mcdaintel.com/post/mcda-second-report-on-extended-external-ecg-payment-policy. As MCDA emphasized, CMS is required under its established processes to specify accurate direct inputs for national reimbursement irrespective of who engaged with the RUC process, and thus should consider information from other AECG providers as relevant.

3. Updated Physician Fee Schedule PE Rate Simulation

118. Building upon its prior analysis of PE rates for Zio XT and similar devices, MCDA examined four scenarios:

a. Rates under the Proposed Rule;
b. The Proposed Rule's rates that excluded iRhythm's SG&A costs from the patch supply input cost;
c. The Proposed Rule's rates that excluded iRhythm's SG&A and R&D costs; and
d. MCDA's main summary recommendation based on the direct costs of the BioTelemetry ePatch 2.0

119. MCDA found that adjusting inflated references used initially for the Proposed Rule, which did not strip out prohibited SG&A and R&D costs, the rates would be $76.28 (7-day) and $87.33 (15-day). As MCDA noted, these adjustments resulted in a final cost in line with comparable calculations based upon BioTelemetry's actual invoices, which resulted in rates of $67.23 (7-day) and $94.78 (15-day).

120. The following chart illustrates MCDA's updated findings:

	Global Code				Scanning Analysis & Report Code			
	CMS 2021 Proposal (incl SG&A and R&D)	CMS 2021 Proposal excl SG&A incl R&D	CMS 2021 Proposal excl SG&A and R&D	MCDA Main Recommendation	CMS 2021 Proposal (incl SG&A and R&D)	CMS 2021 Proposal excl SG&A incl R&D	CMS 2021 Proposal excl SG&A and R&D	MCDA Main Recommendation
>48 Hour - 7 Day Service: Global = 93241 / Scanning Analysis & Report = 93243								
Work RVU	0.50	0.50	0.50	0.50	-	-	-	-
MP RVU	0.07	0.07	0.07	0.07	0.02	0.02	0.02	0.02
Direct Costs - Patch	$ 413.24	$ 105.18	$ 41.17	$ 30.02	$ 413.24	$ 105.18	$ 41.17	$ 30.02
Direct Costs - Total	$ 469.86	$ 161.80	$ 97.79	$ 86.64	$ 457.15	$ 149.09	$ 85.08	$ 73.93
PFS Rate - 2021	$ 414.17	$ 164.01	$ 112.03	$ 102.97	$ 378.43	$ 128.26	$ 76.28	*$ 67.23*
PFS Rate - 2020	$ 433.20	$ 172.64	$ 118.50	$ 109.07	$ 394.25	$ 133.68	$ 79.54	$ 70.11
PFS Rate - 2019	$ 442.10	$ 175.60	$ 120.22	$ 110.58	$ 403.07	$ 136.57	$ 81.19	$ 71.55
PFS Rate - 2018	$ 456.64	$ 180.72	$ 123.39	$ 113.40	$ 417.18	$ 141.26	$ 83.93	$ 73.94
PFS Rate - 2017	$ 452.69	$ 179.25	$ 122.43	$ 112.53	$ 413.44	$ 139.99	$ 83.18	$ 73.28
PFS Rate - 2016	$ 459.40	$ 181.58	$ 123.85	$ 113.80	$ 419.99	$ 142.17	$ 84.44	$ 74.38
PFS Rate - 2015	$ 464.06	$ 183.44	$ 125.14	$ 114.98	$ 424.34	$ 143.72	$ 85.41	$ 75.25
>7 Day - 15 Day Service: Global = 93245 / Scanning Analysis & Report = 93247								
Work RVU	0.55	0.55	0.55	0.55	-	-	-	-
MP RVU	0.08	0.08	0.08	0.08	0.03	0.03	0.03	0.03
Direct Costs - Patch	$ 413.24	$ 105.18	$ 41.17	$ 50.34	$ 413.24	$ 105.18	$ 41.17	$ 50.34
Direct Costs - Total	$ 480.68	$ 172.62	$ 108.61	$ 117.78	$ 467.97	$ 159.91	$ 95.90	$ 105.07
PFS Rate - 2021	$ 427.38	$ 177.22	$ 125.23	$ 132.68	$ 389.48	$ 139.32	$ 87.33	*$ 94.78*
PFS Rate - 2020	$ 447.16	$ 186.59	$ 132.45	$ 140.21	$ 405.79	$ 145.23	$ 91.08	$ 98.84
PFS Rate - 2019	$ 456.25	$ 189.75	$ 134.37	$ 142.30	$ 414.83	$ 148.33	$ 92.95	$ 100.88
PFS Rate - 2018	$ 471.16	$ 195.24	$ 137.91	$ 146.12	$ 429.31	$ 153.39	$ 96.06	$ 104.27
PFS Rate - 2017	$ 467.09	$ 193.65	$ 136.83	$ 144.97	$ 425.46	$ 152.01	$ 95.20	$ 103.34
PFS Rate - 2016	$ 473.97	$ 196.15	$ 138.42	$ 146.69	$ 432.18	$ 154.36	$ 96.63	$ 104.90
PFS Rate - 2015	$ 478.80	$ 198.18	$ 139.87	$ 148.23	$ 436.68	$ 156.06	$ 97.76	$ 106.11

H. Independent Expert Review Corroborates and Bolsters the MCDA Reports' Findings

121. Dr. Freeman is a board-certified ophthalmologist specializing in ophthalmic plastic and reconstructive surgery who is also a Certified Coding Specialist and a Certified Professional Medical Auditor. He holds a Bachelor of Science from the College of Engineering at Cornell University, an M.D. from the University of Michigan Medical School, and an M.B.A. from the University of Central Florida.

122. Dr. Freeman has previously served as an expert witness for both plaintiffs and defendants in disputes that concern Medicare reimbursement rates, auditing, compliance, and CPT codes. He also has served as a member of the AMA's CPT Advisory Committee since 2004 and serves as the Chair of both the Coding and Third-Party Reimbursement Committee of the American Society of Ophthalmic Plastic and Reconstructive Surgery and the Third-Party Liaison Committee of the Florida Society of Ophthalmology.

123. Lead Plaintiff retained Dr. Freeman as a consultant to review and analyze the pertinent facts of this case, including the reimbursement rates identified in CMS' Proposed Rule and the Final Rule, the information provided to CMS during the notice-and-comment period, including both MCDA Reports and iRhythm's response seeking to justify inflated reimbursement rates, facts uncovered in the Delaware Litigation between Bardy and Hill-Rom, and other information relevant to the claims in this Action.

124. After analyzing all relevant facts, including the invoice data that Mr. Muller analyzed and discussed in his detailed Reports, Dr. Freeman concurred with the essential findings and conclusions of MCDA's Reports. Specifically, Dr. Freeman agrees that BioTelemetry's ePatch 2.0 is the most appropriate comparator to the Zio XT, and that the proxy input utilized in the Proposed Rule is not an equivalent comparator. Dr. Freeman further noted an absence of compelling evidence to demonstrate similarities between the Zio XT and the neurostimulator, and in fact, concluded that the direct cost of an implanted sacral neurostimulator is in actuality significantly higher than that for an AECG device. Dr. Freeman agreed with the MCDA's Reports' conclusion that the Zio XT and ePatch 2.0 are largely comparable.

125. Dr. Freeman also rejected iRhythm's false claim that the clinical value and health benefits of the Zio XT could be used to substantiate inflated reimbursement rates under CMS' cost methodology. While clinical value and health benefits may be relevant to whether a device should be covered by Medicare, he emphasized that clinical value is ***irrelevant*** to the task of setting PE rates, which are specified in the Social Security Act, and are based on the relative practice expense resources involved in furnishing the service or group of services.

126. Dr. Freeman also reviewed relevant evidence and expert testimony that came to light through the unredacted record in the Delaware Litigation between Bardy and Hill-Rom. *See* Section M, ¶¶184-92. Dr. Freeman noted that expert and fact witness testimony in that action indicated that the actual, direct cost of AECG devices is, in fact, trending downwards.

127. Moreover, Dr. Freeman concurred with MCDA's conclusion that the reimbursements rates were previously inflated because iRhythm provided claims data to the RUC and the MAC that improperly included prohibited indirect costs such as SG&A expenses and R&D expenses as direct costs.

128. Dr. Freeman also stated that MACs beside Novitas have clearly concluded that the rates sought by iRhythm for valuation codes 93243 and 93247 are excessive. The chart below shows the large discrepancy between the rates set by Novitas before the Proposed Rule was announced and the rates set by other MACs for cardiac monitoring devices:

Medicare Administrative Contractor (MAC) Reimbursement for Zio and Traditional Holter Monitoring, by State

State	MAC	City	0297T	93226	State	MAC	City	0297T	93226
ID	Noridian		$ 33.34	$ 33.34	IL	NGS	Chicago	$ 47.05	$ 38.70
UT	Noridian		$ 34.50	$ 34.50	FL	First Coast		$ 47.20	$ 38.75
KY	CGS		$ 34.95	$ 32.64	CA	Noridian	San Francisco	$ 48.86	$ 48.86
OH	CGS		$ 35.96	$ 34.07	CT	NGS		$ 49.35	$ 41.33
AZ	Noridian		$ 35.99	$ 35.99	MA	NGS	Boston	$ 50.93	$ 43.72
SD	Noridian		$ 36.90	$ 36.90	NY	NGS		$ 51.67	$ 43.96
ND	Noridian		$ 36.95	$ 36.95	WV	Palmetto		$ 171.34	$ 31.97
WY	Noridian		$ 37.08	$ 37.08	AL	Palmetto		$ 183.26	$ 32.89
MT	Noridian		$ 37.35	$ 37.35	TN	Palmetto		$ 185.53	$ 33.31
NV	Noridian		$ 37.71	$ 37.71	SC	Palmetto		$ 187.80	$ 33.72
OR	Noridian	Portland	$ 39.03	$ 39.03	NC	Palmetto		$ 191.59	$ 34.47
IA	WPS		$ 39.25	$ 33.49	VA	Palmetto		$ 201.91	$ 36.57
KS	WPS		$ 39.75	$ 33.71	GA	Palmetto	Atlanta	$ 205.51	$ 37.04
NE	WPS		$ 39.97	$ 33.57	MS	Novitas		$ 267.10	$ 32.11
IN	WPS		$ 40.89	$ 33.92	AR	Novitas		$ 267.99	$ 32.26
AK	Noridian		$ 41.32	$ 41.32	OK	Novitas		$ 269.65	$ 33.10
HA	Noridian		$ 42.35	$ 42.35	NM	Novitas		$ 284.28	$ 34.31
WA	Noridian	Seattle	$ 42.46	$ 42.46	LA	Novitas	New Orleans	$ 304.13	$ 35.97
WI	NGS		$ 42.52	$ 35.30	TX	Novitas	Houston	$ 311.08	$ 37.54
MO	WPS	St. Louis	$ 42.87	$ 35.63	CO	Novitas		$ 312.67	$ 37.80
VT	NGS		$ 44.63	$ 37.53	DE	Novitas		$ 318.85	$ 37.86
MN	NGS		$ 44.71	$ 37.29	PA	Novitas	Philadelphia	$ 336.21	$ 39.98
ME	NGS	Portland	$ 45.37	$ 37.26	MD	Novitas	Baltimore	$ 339.28	$ 40.72
MI	WPS	Detroit	$ 45.72	$ 36.96	NJ	Novitas	North Jersey	$ 365.48	$ 43.71
NH	NGS		$ 46.34	$ 38.79	DC	Novitas	Washington, DC	$ 372.67	$ 44.75
RI	NGS		$ 46.79	$ 38.96					

Source: Medicare Administrative Contractor Fee Schedules, 2019
Note: In states with multiple sub-regions, we used the region with the highest reimbursement rate

129. Finally, Dr. Freeman stated that commercial rates indexed to Medicare decrease if Medicare reimbursement rates decrease. He further stated that commercial rates could fall if assumptions based upon previous Medicare rates do not prove correct.

130. Dr. Freeman's conclusions are corroborated by numerous analysts who reported in 2021 that any cut in the reimbursement rate from CMS or Novitas would also negatively impact commercial rates for the Zio XT because, while not all commercial rates are directly indexed to Medicare rates, commercial rates are generally priced as a multiple of the Medicare rates.

131. For example, on January 31, 2021, an analyst at Baird Equity Research highlighted that, while commercial rates are negotiated independently of Medicare rates, commercial payers tend to follow Medicare's lead and a cut in reimbursement rates for Medicare would place pressure on the commercial rates as well. Mike Polark, *iRhythm Technologies, Inc. (IRTC): Seatbelts Should Remain Fastened,* BAIRD EQUITY RESEARCH, January 31, 2021, at 5. Similarly, on February 2, 2021, analysts from Oppenheimer wrote in an analyst report that a cut in the Medicare reimbursement rates would be followed by a similar reduction in commercial rates. Suraj Kalia & Mike Ott, *iRhythm: Expert Call Highlights Gathering Storm on The Story*, OPPENHEIMER, February 2, 2021, at 1.

132. Moreover, Dr. Freeman's conclusions and the commentary from analysts on this topic are substantiated by prior CMS practice. Between 2009 and 2010, a MAC reduced the reimbursement rates for CardioNet's MCOT device, which led to a corresponding decline in commercial reimbursement rates. *See* Mike Polark, *iRhythm Technologies, Inc. (IRTC): Back to the Future? Revisiting the Mobile Cardiac Telemetry Analog, Again*, Baird Equity Research, April 16, 2021, at 1.

133. Indeed, directly contradicting King's false statements that commercial rates are unaffected by Medicare rates, in a February 26, 2021 earnings call, Coyle admitted that iRhythm was holding rather than processing approximately 90% of 2021 year-to-date Zio XT claims and 50% of those claims were being held because commercial payers had already begun to contemplate renegotiating commercial rates because Medicare reimbursement rates had been slashed. Coyle also conceded that the rate cut made by Novitas may have a potential "bleed over effect on to the

commercial side" of iRhythm's business. On May 6, 2021, Coyle again acknowledged that Medicare rate cuts would impact negotiations with commercial payors, with a particularly negative impact on 2022 if CMS did not establish higher rates, thereby corroborating Dr. Freeman's conclusion.

I. Novitas Slashes Reimbursement Rates

134. Following CMS' delegation of rate-setting to Novitas in the Final Rule, on January 29, 2021, Novitas established calendar year 2021 reimbursement rates for CPT Codes 93241, 93243, 93245 and 93247. Novitas slashed reimbursement rates for the Zio XT from an average of $312 before the Class Period to an average of $77.10 for participating providers, $73.82 for nonparticipating providers and $89.36 for physicians who do not accept Medicare's approved amount as payment in full.

135. Upon the announcement of Novitas' massive rate cut for the Zio XT, the Company's stock price declined by nearly 33% to close at $168.42 on January 29, 2021 from its previous day closing price of $251 on January 28, 2021, on heavy trading volume.

136. Between January 2021 and April 2021, Coyle repeatedly referred to this rate cut as a "mistake." According to Coyle, the new rate was similar to a standard ECG monitoring device that provides only 24 to 48 hours of monitoring, and did not take into account iRhythm's more sophisticated device with longer term monitoring for up to 14 days. However, Novitas has spoken with Mr. Muller several times during early 2021, and Mr. Muller has told Lead Plaintiff that, based on his impressions from those conversations, Novitas did not make any "mistake," and has indicated that it is now sensitive to and conscience about price. Indeed, even assuming that Coyle's claim had any merit, a traditional ECG monitoring device that provides monitoring for less time is a far better proxy to set pricing than the clinically irrelevant and cost inappropriate neurostimulator that CMS, in fact, rejected in the Final Rule for 2021 after the publication of the October 5, 2020 MCDA Report.

137. On February 25, 2021, the Company announced in a press release that it was unable to provide financial guidance to investors due to "uncertainty" related to reimbursement rates. It also held an earnings conference call on the same day to announce the financial results for the

fourth quarter of 2020. On this conference call, Devine and Coyle disclosed that the Company would hold back or not seek reimbursement for approximately 90% of all 2021 year-to-date Zio XT claims, and 50% of that amount related to withheld claims for commercial contracts because, according to Coyle, the Company had not yet reached an agreement and commercial payors had indicated that the Novitas rate cuts were the reason for the failure to reach an agreement.

138. On April 10, 2021, after numerous meetings where iRhythm was afforded the opportunity to identify its objections to the rate set, Novitas modestly revised the reimbursement rates for the Zio XT to approximately $115, a figure that was still over 60% less than what iRhythm reaped before the Class Period, and far less than Defendants' false characterization of Novitas' rate cuts as a "mistake" had led investors to expect.

139. On this news, the price of the Company's stock again plunged by over 39% to close at $80.36 on April 12, 2021 from its previous day closing price of $132.76 on April 9, 2021.

140. In reaction to this negative news, on April 12, 2021, the Company disclosed that the revised rates would have negatively impacted 2020 Medicare revenue by $41.3 million and would have decreased 2020 total company revenue from $265.2 million to $223.8 million, or a decrease of 15.6%. On a conference call to discuss Novitas' updated rates, Coyle told investors that the Company would discontinue serving Medicare patients, but the Company reversed itself and abandoned the plan to exit the Medicare segment in May 2021. Multiple analysts, including those from Morgan Stanley, BTIG and Oppenheimer, observed that the Novitas rates, unless reversed, would create downward pricing pressure on commercial contracts.

J. Disruptions Continue as the Company's Position Becomes More Precarious

141. On June 1, 2021, Coyle abruptly resigned from his position as CEO as well as a member of the Company's Board of Directors, after less than five months of service. Devine replaced Coyle as the Company's interim CEO.

142. On this news, the Company's stock price declined by nearly 18% to close at $62.77 on June 2, 2021 from its prior closing price of $76.25. Analysts reacted negatively to Coyle's abrupt departure and observed that his resignation signaled his (and the Company's) failure to effectively manage the reimbursement crisis. For example, an analyst from Oppenheimer openly

questioned Coyle's self-serving excuse that he had resigned for "personal reasons," and reiterated that: "[t]he sudden upper management shuffle belies more issues behind the scenes. Remember, the CEO was the 'only' hope investors latched onto to get IRTC out of the reimbursement mess." Suraj Kalia, Mike Ott & Shaymus Contorno, *iRhythm: CEO Resignation So Soon Surprising*, OPPENHEIMER, June 2, 2021, at 1. Similarly, analysts from Morgan Stanley reacted negatively to Coyle's departure, and stated that the resignation "introduces further disruption and incremental uncertainty . . . " and "we do not see a clear path to material reimbursement upside at this time." Cecilia Furlong & Calvin Chu, *iRhythm Technologies Inc: CEO Transition Injects Another Layer of Complexity*, MORGAN STANLEY, June 2, 2021, at 1.

K. The Proposed Rule for 2022 is Released

143. On July 13, 2021, CMS released the proposed rule that includes updated payment policies, payment rates, and other provisions for services provided to be effective on or after January 1, 2022.

144. In the proposed rule for calendar year 2022, CMS "remain[ed] concerned that we continue to hear that the supply costs as initially considered in our CY 2021 PFS proposal are much higher than they should be." External Extended ECG Monitoring (CPT Codes 93241, 93242, 93243, 93244, 93245, 93246, 93247, and 93248), 86 Fed. Reg. 39178 (July 23, 2021). CMS again sought public comment and information from all stakeholders regarding "fair and stable pricing for these services." *Id.* at 39179. It again emphasized that relevant information such as actual invoices, a more appropriate proxy input or other pertinent information "would be ideal for us to use in establishing fair and stable pricing for these services." *Id.* Yet again, CMS stressed that "in the absence of such additional and actionable information (***that is, information that provides further context to information that has already been considered***) we are proposing to maintain contractor pricing for these services." *Id.* (Emphasis added).

145. Defendants told investors that they had met with CMS personnel during the Class Period in early 2021 in an effort to convince the government to set higher, national reimbursement rates and circumvent the adverse decisions from Novitas. To this day, Defendants continue to conceal the specifics of their communications with CMS to investors, but the proposed rule for

2022 now makes clear that CMS was not persuaded by their excuses. As a result of the proposed rule for 2022, iRhythm continues to be stuck with the noninflated rates set by Novitas in April 2021.

146. The market again reacted negatively upon the release of the new proposed rule for 2022. On July 14, 2021, the price of the Company's common stock declined by nearly 9% to close at $53.90 from its previous day closing price of $59.07, on heavy trading volume.

L. Defendants' False and Misleading Statements and Omissions

147. The Class Period begins on August 4, 2020 when Defendants held a conference call to discuss CMS' Proposed Rule for the PFS effective on January 1, 2021. On this conference call, King was directly asked about the lack of an invoice to support the costs of the Zio XT and the clinically irrelevant proxy input contained in the Proposed Rule, and King provided the following false and misleading response:

> **Q: Suraj Kalia**
>
> Perfect. So Kevin, help us understand for November when the final rates come out a read of the current proposal. Specifically, they're talking about a crosswalk comparison with percutaneous neurostimulation leads which, by definition, are more resource-intensive. ***And they also say that this is not clinically appropriate, but they do not have -- I forget what the words were -- they don't have invoicing for extended patch monitors. When CMS is specifically saying that this is not a clinically appropriate comparator, how confident are you all that this will be maintained in November in the final proposal -- in the final rule and then move on to Jan 1 implementation?***
>
> **A: Kevin King**
>
> We're very confident in the data that was provided, and we're very confident in the calculation of the RVU. The crosswalk of the supply is a reflection that our business model is not a typical business model in that we are the developer, the manufacturer, the supplier and the provider of the service. So there is no sale of iRhythm to iRhythm. It's just one integrated service. ***And so we worked hand-in-hand, as referenced in the CMS note, and we provided over 500,000 invoices to CMS for our service across a wide range of contracted arrangements, commercial carriers, noncommercial carriers, patients have paid out of pocket, CMS rates and everything, and those were all used.***
>
> At the end of the day, they wanted to find something that was equivalent in supply cost, and they chose this factor of this neurology [chit] or what was described there.

> The calculation of a PR -- PE RVU is very complicated, involves over 2 dozen steps to calculating that, and there are numerous adjustments, including reductions of direct and indirect costs and a whole variety of assumptions on who utilizes it by specialty such that there's a net reduction. ***And I think that calculation was done well, and we'll support it. And I'm confident it's what CMS wanted, and that's where we've got the rates. I'm not concerned about that changing.***

148. The statements identified in Paragraph 147 were materially false and misleading when made because (a) iRhythm did not provide any "invoices" (let alone 500,000) as King falsely claimed, but instead only provided claims data that was inadequate and could not substitute for actual invoices; and (b) the statements omitted the following facts, each of which was necessary to make the statements not misleading under the circumstances in which they were made: (1) the neurostimulator referenced by the analyst that was used as a proxy input or "crosswalk" was used only because it was the closest supply item in price and CMS emphasized that an actual invoice would be required for the Final Rule; (2) the neurostimulator was a grossly inadequate comparator because its actual direct costs are far higher than the Zio XT's; (3) iRhythm's inflated reimbursement proposal included prohibited indirect costs such as SG&A expenses and R&D expenses; and (4) the largest cost component of the Zio XT was the device itself, which was trending downwards and therefore could not substantiate any increase in reimbursement.

149. On August 6, 2020, iRhythm held an earnings conference call to announce the financial results for the second quarter of 2020. On this earnings conference call, King was specifically asked by an analyst whether the Company would provide CMS with an actual invoice to support the costs and reimbursement rates for the Zio XT, and King made the following materially false and misleading statements in response:

> **Q: Suraj Kalia**
>
> Got it. Now it's clearer. And Kevin, one last and I'll hop back in queue. ***I presume you will be supplying the invoices for various components to CMS before the final reimbursement rule comes out.***
>
> **A: Kevin King**

> ***Sure. As I said on the call, I think it was yesterday, we provided to CMS over 500,000 invoices for our service across contracted, non-contracted, Medicare, self-pay, client bill.*** They have full access of all various and sundry types of payments over an extended period of time. ***And they have everything they can get from us.***

150. The statements identified in Paragraph 149 were materially false and misleading when made because (a) iRhythm did not provide any "invoices" (let alone 500,000) as King falsely claimed, but instead only provided claims data that was inadequate and could not substitute for actual invoices; and (b) iRhythm had not provided CMS "everything they can get from us," but instead withheld highly critical actual cost data for both its device and its analytics.

151. On the August 6, 2020 earnings conference call, another analyst pointedly asked King whether there was a risk that reimbursement rates could change between the announcements of the Proposed Rule and the Final Rule for 2021 and King made the following materially false and misleading statements in response:

> **Q: Gene Mannheimer**
>
> Wow. Okay, that's great. Okay. ***And another question on, I guess, how things can change between now and December. Historically, does the reimbursement tend to change from the proposed rule to the final rule? And if so, has it veered very much from that proposed rule?***
>
> **A: Kevin King**
>
> I think the big factor here, I guess, is the conversion factor that all of the RVUs and the physician payment system get multiplied by to arrive at a price point. And what was proposed in the rule here was about a 10.6% decrease in conversion factor across all categories, not just the code set that we use but for everything. And my guess is that, that is going to be heavily debated. It's a fairly large decrease. And I think in prior years, it's been nowhere near that level. There is a reason for that. And it's my understanding, I'm hoping I'm correct, but physician payment for codes that are called evaluation and management, E&M codes, went up substantially and that CMS is required to operate a balanced budget format, so they can't just pile on more expense.
>
> They have to when something goes up, something else has to go down. And it seems like the best way that they were able to facilitate that was to just drain more water out of the pool through the conversion factor. So my suspicion is in the budgeting

process, that's going to be highly debated. ***As far as on the code structure side, I the process was so thorough and so complete, I'm hoping that there's not much to change. But of course, there's the comment period. And we'll see what happens.***

152. The statements identified in Paragraph 151 were materially false and misleading when made because (a) King was aware of but concealed that CMS rates often change between proposed and final rules; (b) the rate-setting process was "not thorough and complete," but was instead hindered because iRhythm failed to provide a complete invoice with a breakdown of costs as required; and (c) because the claims data submitted by the Company to CMS had already been rejected as inadequate before these false statements were made.

153. On August 13, 2020, King participated in the Canaccord Genuity 40th Virtual Annual Growth Conference where an analyst specifically asked about the impact that reimbursement changes would have on the Company's business, and King made the following materially false and misleading statements in response:

Q: Cecilia Furlong

Great. And I guess, just in the last five-minutes, ***I definitely want to touch on reimbursement, kind of an epilogue following the past several years. But can you just touch on the recently proposed codes, changes to reimbursement, and impact on your business?*** But then also, just the shift from a single set of codes to two, and what that implies or may imply about the value proposition of long-term wear monitoring?

A: Kevin King

Sure. Well, that's – decision is nearly behind us, right? The initial ruling was put out by CMS on August 4 and 5. ***Look, we believe that the decision was built on a foundation of clinical evidence, that longer term monitoring is superior, and from a diagnostic standpoint, and that it quite often changes medical treatment decisions.***

We have a very long standing collaboration or history of collaboration with medical societies as well as CMS; these played into it. And the decision that came out from a prescribing mix and payor perspective. If we apply those to our 2019 revenues, our 2019 revenues would increase by high single-digits. ***And so this is a really favorable ruling, and it was a burden off of our shoulders right now because a lot of people were betting against use or thinking that the risk were high. And I would just***

> ***reiterate that for the last four years, as I've spoken to you and to many others in your shoes, we've always been confident that our reimbursement rate will be the same or go up. And we believe, it stood the evidence in the fact base that we have.*** So we're really, really happy with that. It is an initial ruling, so there's a common period that takes place between now and sometime in early December, before it becomes final.

154. The statements identified in Paragraph 153 were materially false and misleading when made because (a) the decision was not "nearly behind us" but was instead embroiled in a vigorous debate at the time; (b) the rate decision that CMS indicated was to be made in a final rule was not a matter of "clinical evidence" but rather actual costs, which iRhythm actively concealed by refusing to provide cost invoices as requested by CMS; (c) contrary to King's false statements, the risk of an adverse ruling from CMS remained very high because Defendants had not provided actual invoice data to justify the costs of the Zio XT; and (d) the inflated reimbursement rate was not supported by "evidence in the fact base that we have," and instead was undermined by evidence that: the inflated rates in the Proposed Rule included prohibited indirect costs such as SG&A expenses and R&D expenses, and the single biggest cost component of the Zio XT, the device itself, was trending downwards.

155. On November 6, 2020, the Company held an earnings conference call to announce the financial results for the third quarter of 2020. On this conference call, King was directly asked whether anything had changed that would put the reimbursement rates identified in the Proposed Rule at risk, and King made the following materially false and misleading statements in response:

> **Q: David Lewis**
>
> ***The first would just be any update on the reimbursement process, Kevin, other than the commentary you've already provided sort of in the public domain would be question number one.*** And then question number two for me would just be, as you think about -- it's early, but as you think about 2021, I know there's a lot of dynamics moving around from reimbursement from a revenue perspective. But, if you think about the underlying volume of the business, I'm just trying to think about how we should think about sort of '21 over a baseline 2019 and is sort of 25% volume growth for this business, sort of the right structural growth rate that you're seeing? Thanks so much.

A: Kevin King

Yes. Hi, it's Kevin. ***Really don't have any other updates on reimbursement than what we said here in the prepared remarks and the comments that we've had since the open period closed. We remain extremely confident in where we sit. We've provided all of the necessary information and feedback, and we're looking very forward to December 1st when the final ruling takes place.***

156. The statements identified in Paragraph 155 were materially false and misleading when made for the same reasons identified in Paragraphs 152 and 154. In addition, King failed to disclose the following facts that made his statements further misleading under the circumstances in which they were made: (a) that the release of MCDA's Report in the notice-and-comment period had put the excessively high reimbursement rates for the Zio XT at risk; and (b) that the Company had failed to dispute MCDA's findings that invoices from iRhythm's direct competitors showed that the Zio XT's actual costs were far lower than the reimbursement rates the Company wanted CMS to endorse, and the fact that the Company improperly included prohibited indirect costs such as SG&A expenses and R&D expense to support the Proposed Rule's inflated reimbursement rates.

157. On December 1, 2020, CMS released the Final Rule for the PFS effective on January 1, 2021. In the Final Rule, CMS repeatedly emphasized the need for a representative invoice to establish commercial pricing, acknowledged the severe criticisms of the October 5, 2020 MCDA Report, refused to adopt national pricing due to those criticisms, and instead delegated the authority to set reimbursement rates back to Novitas. In response, Defendants held a conference call on December 2, 2020 to discuss CMS' Final Rule, and King made the following materially false and misleading statements:

While we were expecting a national pricing decision, it's very important to note, this is not a rate cut rather a rate increase was not approved and the changes relate to roughly one quarter of our revenue. We believe a local contracting path is an attractive and familiar option for the company, and leverages the long-standing working relationships we have with several local contractors. ***Separate but related, we believe our commercial contract pricing is unaffected, as is our ability to pursue Medicaid contracting and reimbursement for our home enrollment service. And***

> ***most importantly, the clinical validation that is associated with the Category I codes, the CPT codes remain and we believe this positions us well to improve patient access and physician willingness to adopt the technology.***

158. Analysts understood this statement to mean that the Company did not expect any downside risk of a rate cut. For example, an analyst report from William Blair published on December 2, 2020 observed that "[m]anagement believes that contractor pricing could remain in place for the next two years at least," and another analyst from J.P. Morgan observed on the same day that "to be clear this isn't a rate cut, but rather a proposed increase isn't confirmed; there's a big difference." Margaret Kaczor, Brandon Vazquez & Maggie Boeye, *iRhythm Technologies, Inc.: Reimbursement Update Adds Back Overhand, but Fundamentals Strong for This Leader in Digital Health*, WILLIAM BLAIR, December 2, 2020, at 2; Robbie Marcus, Allen Gong, Lilia-Celine Lozada & Sarin Murlidar, *iRhythm (IRTC US): Buy the Dip; Reverting to Contractor Pricing Is a Minor Setback and Doesn't Take Better Pricing Off the Table*, J.P. MORGAN, December 1, 2020, at 1.

159. The statements identified in Paragraph 157 were materially false and misleading when made because: (a) CMS' rejection of an unsubstantiated and inflated rate affected (directly and indirectly) ***nearly all*** of the Company's revenue, not just 25%; (b) commercial contract pricing was not "unaffected"; (c) the local contracting (*i.e.*, rate setting by MACs) path was not "attractive," but was in fact undermined by proof contained in the October 5, 2020 MCDA Report that the inflated reimbursement rates previously under consideration for the Zio XT were grossly inflated; and (d) King's references to "clinical validation" were misleading because clinical value is irrelevant to the task of setting reimbursement rates.

160. After his prepared remarks, Kevin King took questions from analysts and was immediately asked if CMS' decision meant that iRhythm was "back to ground zero":

Q: David Lewis

Okay. And just maybe two more for me. The first one, Kevin is just, the reimbursement made obviously had stemmed for, for years and you can argue even goes back to the pre IPO days. ***So, some are got conclude this decision sort of suggests that we're back to square zero, and we're kind of starting over. If based on sort of the RVU information and the proposed rule from CMS and how this process is played out? What would you say to investors, who believe you are kind of back to ground zero? And why is that or is not the case?***

A: Kevin King

Well, I don't think we're back to ground zero. I think we've made tremendous progress here. We have a permanent CPT code, codes, code sets that have replaced temporary codes. We have communicated, and it has been supported that evidence generated by iRhythm is superior to other methodologies that have created a new category.

There's widespread acceptance and adoption of the technology, digital technologies including Artificial Intelligence. ***I think the challenge is, as I described, CMS has a rather rigid framework that requires precise inputs like an invoice that don't exist in these categories. And it's our job to help them to remodel or to affect change such that not only iRhythm, but every other digital health company and every other subscription service company and healthcare, can get the benefit of fairly valued remuneration.***

So, I don't think we're back at ground zero at all, I'm extremely confident. And importantly as I said look, this is not a rate cut. This isn't a price increase per se. And I'm extremely confident of where we are. Disappointing we didn't get across the finish line on this particular point, but our relationships with AMA, CMS, all of these organizations are good. We intend to continue to collaborate with them and try to push this forward, not only for us, but for the industry.

161. The statements identified in Paragraph 160 were materially false and misleading for the same reasons identified in Paragraph 159. In addition, the statements identified in Paragraph 160 were materially false and misleading when made because (a) CMS' rejection of national pricing and delegation to MACs did, in fact, put iRhythm "back at ground zero"; (b) this effectively ***was a rate cut***, as CMS indicated it could not substantiate the inflated rate under consideration, but the Final Rule delegated the rate-setting decision which would determine the extent of the rate cut to MACs like Novitas; (c) actual inputs do exist in those categories of services, as demonstrated by

MCDA's examination of an actual invoice from BioTelemetry's ePatch; and (d) the statements omitted to disclose the following facts that were necessary to make the statements not misleading under the circumstances in which they were made: (1) that the data iRhythm submitted to the RUC and CMS included prohibited indirect costs for SG&A expenses and R&D expenses; and (2) that iRhythm had little incentive to provide an actual invoice because the biggest cost component of the service, the Zio XT device itself, was trending downwards.

162. On the conference call held on December 2, 2020, King was directly asked why Defendants contended that the reimbursement rate would not go down, and King made the following materially false and misleading statement in response:

> **Q: Robbie Marcus**
>
> Got it. And then, one of the most common questions I've gotten overnight this morning is, what gives you confidence, that when you go back to the MACs really Novitas and Noridian to begin early next year to discuss the rate going forward, that it should be, sort of a status quo with maybe, the bulk case of some upside to or book ended between the CMS rate that was proposed. ***What gives you confidence the rate won't go down? And it's really just a price increase wasn't affirmed rather than something of a price cut? Thanks a lot.***
>
> **A: Kevin King**
>
> ***Yes.*** I think it comes to the long-standing relationships, where we have with these administration centers or local contractors. In both cases Noridian and Novitas and to some extent Palmetto on the East Coast, these things stand back almost seven years of working relationships.
>
> I wouldn't say, on a day-to-day basis, but pretty deep. They understand our technologies. Our technologies have been validated. We've been audited by these organizations in the past and we've used the RUC process with Novitas the first go round. ***And now we have new data that came out of the initial ruling that we intend to use. So, that gives me confidence that we're going to be -- we're going to be shooting for that for the higher end of where we were. I don't know if we'll get there. I hope we do. But that's certainly where the discussions will begin. And there isn't really a basis for them for lowering if there isn't any new data that would suggest that the price of our service would be less.***

163. The statements identified in Paragraph 162 were materially false and misleading when made because (a) there was in fact "new data that would suggest that the price of our service would be less" as outlined in the October 5, 2020 MCDA Report; and (b) there were multiple "bas[e]s for them for lowering" reimbursement rates including that iRhythm added prohibited indirect costs such as SG&A expenses and R&D expenses to inflate the reimbursement rates initially discussed, that the inflated Proposed Rule rate was in part influenced by a comparison service that was not in fact comparable, and that the actual cost of the Zio XT was, in fact, trending downwards.

164. Another analyst again pointedly asked King whether the setbacks from the Final Rule would impact the rates paid by commercial parties, and King made the following materially false and misleading statements in response:

> **Q: Kaila Krum**
>
> Hi guys. Thanks for taking our questions. ***So, you've mentioned this has a direct impact on about 1/4 of your revenue. How does this impact your relationships with private payers and/or sort of the balance of your revenue base?***
>
> **A: Kevin King**
>
> ***I don't believe it does*** and we've commented on this in the past when we described the initial ruling or the benefits of the initial ruling where we said crosswalking the 2019 revenue to the initial ruling would take us up in high single digits, and that was largely CMS. ***And we did not believe that the commercial contracts that we have in place would largely be affected mostly because they were already paying higher than where we were and higher than the initial ruling ones. So I'm not overly concerned about that. Many of these contracts are already completed and have been crosswalked to the existing commercial rates that we have.*** So, I'm feeling pretty confident about that.

165. The statements identified in Paragraph 164 were materially false and misleading when made because CMS' rejection of an unsubstantiated and inflated rate affected (directly and indirectly) ***nearly all*** of the Company's revenue, not just 25%, and because commercial contract

pricing was at serious risk of a reduction within the next few years as commercial payors renegotiated their contracts as a multiple of the reduced Medicare rate.

166. When asked directly whether the Final Rule would cause greater unpredictability, King made the following materially false and misleading statements in response:

> **Q: Kaila Krum**
>
> No, you're fine. I just had one final question. ***Just in terms of your expectation going into next year does – I mean does this change sort of make the reimbursement process slower or more sort of unpredictable, just would love to get your thoughts on that?***
>
> **A: Kevin King**
>
> Help me understand a little bit more of that. Going into next year does this make the conversion of the commercial contracts faster or slower? That's your question?
>
> **Q: Kaila Krum**
>
> So, I guess, I mean, does having to go through sort of the MACs make the reimbursement process slower or more sort of unpredictable versus having the established rate and everything in place. It almost seems like, the ability to be able to go to Novitas and have those discussions is almost like a more of the same. And shouldn't impact the reimbursement process make it slower or unpredictable, but just want to clarify that comment.
>
> **A: Kevin King**
>
> Yes. As I said earlier, ***I don't believe this is going to be a challenging process.*** It is going to take some time. And as I said in the prepared remarks, we're going to work on that, and it's going to take a few months. But aside from that, I think this should be fairly straightforward conversation. ***The data is already available,*** the relationships are in place with numerous local carriers, and we'll try to contract with as many as possible to establish the right pricing level. ***And I don't -- and it's about a quarter of our business. I don't see any impact to volume. I don't see any impact to commercial contracting rates so aside from the few months to get in line with the local carrier pricing calendars, I don't think this is going to be terribly disrupted to us.***

167. The statements identified in Paragraph 166 were materially false and misleading when made for the same reasons identified in Paragraphs 159, 161, 163, and 165.

168. On February 25, 2021, iRhythm held a conference call to announce the financial results for the fourth quarter of 2020. At this conference call, Coyle, the new CEO of iRhythm, was again directly asked about the lack of a representative invoice that could support higher reimbursement rates, and Coyle made the following materially false and misleading statements in response:

> **Q: Suraj Kalia**
>
> Got it. Mike, you mentioned about the consortium you met with Novitas, I believe, a couple of weeks ago. Forgive me, if I got that wrong. ***The fundamental question, I think so, all of us are trying to figure out, were any invoices provided by any of the participants in this -- in these meetings, that seems to be sort of the hiccup in this whole process that could yield tangible results pretty quickly. I'd love to get your comments on that.***
>
> **A: Michael Coyle**
>
> So I think one of the benefits of having the fourth largest producers of the -- or suppliers of the service available. And the four companies who are involved in these discussions represent about 97% of the building under the old temporary code with iRhythm frankly representing about 85% of that. But all of the major players who actually provide the service as called out for the code were there. And all of us were able to identify the key components of being able to successfully deliver that service as inclusive of a patch technology that can reliably provide 14-day data with high patient compliance and is labeled as such by the FDA. That when you start to talk about that length of a period of time for collecting, but is essentially 1.5 million cardiac cycles that then have to be analyzed, doing that in the manual process or with the base Holter-like-software approach simply doesn't work because of the complexity and massive amount of data that's being analyzed. ***So having an advanced analytic platform and in our case driven by AI and machine-learned algorithms is critical to being able to have an efficient identification in a sensitive way of where there could be potentially risk -- high risk rhythms in that 14-day code. You may only be looking for five to eight minutes of time over that entire period. It's being able to find it with high sensitivity requires these advanced analytics.***
>
> ***And then, once those areas of potential risk or -- of concerned parts of the electrogram, you need a team of highly trained individuals who could then look at those data and make conclusions about in our case, 13 different potential arrhythmias that could exist versus what you would typically see with the Holter, which is about four. So the idea of a catch being identified at some cost point that isn't part of a fully integrated system. It isn't going to get you the fundamental report that is what becomes useful for the physician enabled in determining***

> ***whether there is actionable rhythms there and what that action should be. And obviously, that's where the fully integrated long-term ECG technology comes in. And all of the players in the space would point to the fact that having these fully integrated systems is what's important to be able to get the outcome that the code is looking for.***

169. The statements identified in Paragraph 168 were materially false and misleading when made because (a) the alleged advanced "analytic platform" and "machine learned algorithms" that Coyle spoke extensively about are indirect costs that CMS has disallowed for more than a decade; (b) iRhythm could, but chose not to, provide an invoice that broke down these costs; (c) iRhythm sought to recover costs for the hardware and software components that were dramatically out of line with the most complex components reimbursed in past PFSs; and (d) the largest component of the cost was the production cost of the Zio XT itself, which was trending downwards before Coyle made these misleading statements.

170. On February 26, 2021, iRhythm filed its Annual Report on Form 10-K for the full fiscal year 2020. Defendants Coyle and Devine signed this Annual Report, and it contains their certifications pursuant to the Sarbanes-Oxley Act of 2002. The Annual Report misleadingly discussed hypothetical risks such as: "policy affecting Medicare coverage and reimbursement relative to our Zio service ***could*** have a material effect on our performance," "changes to the coverage, method and level of reimbursement for our Zio service ***may*** affect future revenue," and "changes in public health insurance coverage and CMS reimbursements for the Zio XT service ***could*** affect the adoption and profitability of our Zio service." (Emphasis added). Such statements were materially false and misleading when made because many of these risks had ***already*** materialized, including a massive rate cut initiated by Novitas in January 2021, and Defendants had no legitimate basis to seek inflated reimbursement rates from CMS or the MAC before such false statements were made.

171. On April 10, 2021, following numerous meetings with iRhythm and other industry participants, Novitas revised its reimbursement rates, but still set them over 60% below what they were before the Class Period, effectively devastating the Company's business. In response, Defendants Coyle and Devine held a conference call to discuss Novitas' revised rates. At this conference call, Coyle was asked by an analyst about how the Company could help drive Novitas' rates higher, and Coyle made the following materially false and misleading statements in response:

> **Q: Cecilia Furlong**
>
> Great. Thanks for taking my question. I guess just first off curious on just discontinuing service to Medicare, how should we be thinking about the time to fully implement? And how long do you hold Medicare claims as you continue your negotiations with Novitas? ***And I guess near-term to what can you see really driving Novitas payment higher?***
>
> **A: Michael Coyle**
>
> […] So that will be sort of job one, but then we will be very interested to understand their methodology. ***Obviously as I mentioned they haven't spoken to us about how pricing was being established. I think we all know the history here that the difficulty here in the physician area is that basically it's a cost based model. They're assuming a physician in practice buying at arm's length technology and then applying it in their practice and using the invoices associated with those individual purchases to be able to establish fair pricing or fair cost inputs to establish pricing. It's obviously very different for us. And frankly the other providers of fully integrated services in long-term ECG were in fact there is substantial internal investment that has gone in the development of the advanced AI algorithms 750,000 hours of ECG data that are driving our ability to do real-time applications of analysis, the ability to actually have a tiered cardiac technician organization that can basically triage simpler to more complex rhythms to be able to very efficiently process which turns out to be 20,000 minutes of ECG data for every record that comes in on a 14-day case.***
>
> ***So, there are significant cost impacts -- inputs that we simply can't provide the invoices for because we're doing them internally and we've obviously tried an alternative methodology here with the rug process to use the arm's length negotiations we have in the commercial pay segment of our market to establish what those commercial payers view as the appropriate value of that overall offering including Medicare advantage, right, which basically has as we showed in public data in the rug process, generally pays $300 for that service.***

172. The statements identified in Paragraph 171 were materially false and misleading when made for the same reasons identified in Paragraphs 169. In addition, Coyle's statements were materially misleading because: (a) Novitas had spoken to iRhythm about "how pricing was being established"; (b) iRhythm had actual knowledge that pricing would be based on actual costs and not clinical outcomes; (c) iRhythm could provide invoices reflecting actual cost information if it was in its interest to do so, but refused since such invoices would not substantiate the inflated rates it advocated; and (d) references to "alternative methodologies" was misleading because Coyle omitted to disclose that iRhythm sought to recoup impermissible SG&A and R&D costs and thus could not possibly substantiate a price increase.

173. On May 6, 2021, iRhythm held an earnings conference call to announce the financial results for the first quarter of 2021. On this conference call, Coyle was asked about Novitas' reimbursement methodology, and Coyle made the following materially false and misleading statements in response:

> **Q: Cecilia Furlong**
>
> Great. I guess I wanted to start off with just really what shifted in terms of what Novitas was looking at pre the rates coming on initially versus the conversations you've been able to have with them subsequent to that. Just really what kind of changed in how they were looking at this, what you were able to bring to the table show them now and kind of their acceptance and willingness to move forward?
>
> **A: Michael Coyle**
>
> So thanks, Celia, for the question. ***The methodology that Novitas is using is very much rooted in sort of a pure cost analysis. And it's based really on what they view as direct product costs, which I think, as you know, that is just the start of the story for the Zio service and that there are significant sort of additional expenses that fall into the OpEx category that come along with things like the bad debt expense that we see with patients with the customer service side of actually having patients putting these -- applying the technology in the at-home setting.***
>
> ***Revenue cycle management investment in terms of processing of claims and dealing with levels of claims rejection. And so what we've tried to do with them is basically identify the costs that they have acknowledged and then to bring into the***

> ***picture of these other costs that have not been acknowledged, including and very importantly, the costs associated with the development of the deep learned algorithms that are key to being able to do this service from the standpoint that 20,000 minutes of electric cardiogram information cannot be done using traditional Holter approaches and brute force analysis of those waveforms.*** They've got to be processed in a way that really find the needle in the haystack and then allow the physician to see exactly what arrhythmias are taking place over that time period.
>
> And it's that, of course, benefit that turns what Holter's 24% diagnostic yield into something closer to 97% when you use the Zio system. So that ability to have the patient identified the first time with the appropriate arrhythmias and then allow them to be treated without a lot of waste in the system is what we're kind of pointing them to. ***So coming up with alternative methodologies that actually will look not just at those direct product costs, but the broader variable cost that go into providing the service and some of these important investments in technology, software, our 750,000-hour database that actually allows the deep-learned algorithms to develop and getting some cost allocations associated with that into the analysis. And we're -- this is not a unique issue for us. There are other areas of the physician fee schedule, and I would point to things like clinical diagnostics, genetic testing, where they have very similar issues, where there are very expensive capital investments made both in manufacturing as well as in the R&D activities that need to be reflected in the calculation of the cost.*** And there have, in fact, been alternative methodologies that have been generally accepted across the MACs in these areas that we are now suggesting would be appropriate models to relook at. And that's exactly where we are in discussions with them, that we think can take this first step and get us to a more reasonable representation of the true products and providing the service.

174. The statements identified in Paragraph 173 were materially false and misleading for the same reasons identified in Paragraphs 169 and 172.

175. On June 2, 2021, Defendant Devine attended the William Blair 41st Growth Stock Conference. At this event, Devine was specifically asked about the Company's outlook on reimbursement rates and any potential impact on commercial contracts due to the Novitas rate cuts, and Devine made the following materially false and misleading statements in response:

> **Q: Margaret Kaczor**
>
> Fair Enough. Thanks, Doug. Yeah. I guess there is a few things to go down. ***Should this signal anything in terms of the outlook for reimbursement, any kind of change in probabilities, whether it's the summer of this year or does that remain the same as it's been? And then kind of a similar question for commercial perspective because Mike was hired as the commercial guy. So***

does this change anything beyond yesterday's plan or January's plan? You guys talked about international launches and so on. So can you still leverage some of those relationships as well?

A: Douglas Devine

Yeah. We're thinking the -- first of all, starting off with the reimbursement, we've -- at the earnings release, I think we did -- in Q1 earnings release, we did a very thorough job of outlining our reimbursement strategy. The three-pronged continuing to work with Novitas, working with CMS on national pricing, engaging with other MACs, engaging with often at cost models that we think will be easier for -- may help the decision makers get to this type of decision and understanding our value better.

There has been no change -- there is no substance of news, progress has been good, executing on all the three of those strategies. We continue to take good meetings and have good dialog with multiple MACs and CMS as we go through the process. As we've said before, I mean, every time we take a meeting, we don't consider that. We're not going to get into the tennis match. We don't consider that material information, but I can definitely assure you that everything has stayed on track to our expectation. Since earnings release, we've had a number of meetings with a number of different entities. And this does not in any way reflect the difference in our opinion on what the outcome and what the chances of how we'd be handicapping the chances of various outcomes in the reimbursement process.

On the commercial process, things have been very stable -- things have been stable. As we highlighted before, we've got about 10% of our payers that are still in negotiations that continues to be the case. We have not seen shift in commercial. And as we said, we do think that the more meeting commercial discussions are really going to be occurring more around the year end and versus we were not expecting to see other commercial negotiation come up and when we our talk track in the Q1 earnings release and hasn't been a change from that in between now and then, we're still forecasting.

176. The statements identified in Paragraph 175 were materially false and misleading when made for the same reasons identified in Paragraphs 169 and 172, and because "progress" had not been "good" and the Company had not had the claimed "good meetings…and good dialog" with MACs and CMS regarding the Company's attempt to restore inflated pricing as an "alternative" to the standard cost-based approach.

177. At the William Blair 41st Growth Stock Conference, Devine was also asked whether iRhythm's alternative strategies to seek inflated reimbursement rates was acceptable under current law, and he made the following materially false and misleading statements in response:

> **Q: Margaret Kaczor**
>
> Okay. ***Got a couple more here in terms of kind of one, do you expect or think your cost effectiveness argument can be accepted by the MACs or CMS under current law?*** And then any other greater detail on the use of the strategies for the clinical lab fee scheduled to inform rates under a physician fee schedule?
>
> **A: Douglas Devine:**
>
> ***Well, it's certainly allowable under the law type of questions. As I mentioned, the cost models that we're moving to are ones that have been used by multiple MACs and multiple cost curves. So I think that's the best answer I can give to that point. But we're not reinventing the wheel here, we're not trying to move into unbroken ground. We're trying to leverage best practices and best practices here.*** In terms of the outcomes, I think we've talked about it in the earnings release as thoroughly as we can. And I'm confident we're doing the right things, but at the same time as I emphasized before, there the transparency on how the final decisions are made is very limited, and we're going to find out about things at the same time that the rest of you do. We're going to find out the final decision at the same time rest of you do.

178. The statements identified in Paragraph 177 were materially false and misleading when made for the same reasons identified in Paragraphs 169, 172 and 176, and because (a) existing law did not allow iRhythm to recover impermissible costs for SG&A and R&D expenses; (b) CMS had already deemed technology related expenses as indirect costs in the past; and (c) the Company was, in fact, trying to break new ground with its attempt to seek impermissible, indirect costs from CMS.

M. Additional Allegations of Scienter

1. CMS' Past Practices Put Defendants on Notice That the Risk of a Rate Cut Was High

179. Industry participants including Defendants knew that iRhythm's attempt to include prohibited, indirect costs for the Zio XT to support inflated reimbursement rates was impermissible,

not just from published cost methodology but because it had been tried—and rejected following public notice and comments—a decade before.

180. In 2008, CMS requested comments on a new CPT Code for 2009—code 93229—that covered wearable mobile cardiovascular telemetry with electrocardiographic recording, concurrent computerized real time data analysis and greater than 24 hours of accessible ECG data storage. This CPT Code related to cardiac monitoring devices provided by LifeWatch and CardioNet.

181. Both LifeWatch and CardioNet argued that CMS' standard pricing methodology was ill-equipped to establish the correct direct costs for their devices because it did not properly account for the high cost of complex software and hardware that received, analyzed, and stored ECG data from patients. LifeWatch and CardioNet also implored CMS to disregard its standard methodology, and instead allow reimbursement for indirect costs associated with a centralized monitoring system that provides services to multiple patients at once instead of only one specific patient at one time.

182. In the notice-and-comment periods—in a prelude to iRhythm's own arguments a decade later—industry participants argued that the clinical benefits of the device justified higher reimbursement rates, and that CMS' standard cost methodology "does not work for remote cardiac providers whose businesses are structured differently from physicians' practices and, as a result, the [RVUs] assigned to the services do not reflect their proper relative cost." J. Remote Cardiac Monitoring Services (CPT codes 93012, 93229, 93268, and 93271), 75 Fed. Reg. 73308 (Nov. 29, 2010). Commenters supportive of the industry further argued that the centralized monitoring system at the heart of the devices is inherently different than other indirect expenses that are used to run a practice, and therefore should not be calculated as an indirect cost. *Id*.

183. CMS thoroughly and conclusively rejected these arguments. In the final rules that set payment policies and reimbursement rates for the PFS in 2011 and 2012, CMS repeatedly stated that "we believe it is more appropriate to classify the costs associated with the centralized monitoring equipment, including the ***hardware and software, workstation, webserver, and call recording system, as indirect costs*** to services furnished to individual patients in a manner that

adequately reflects the number of patients being tested." J. Remote Cardiac Monitoring Services (CPT codes 93012, 93229, 93268, and 93271), 75 Fed. Reg. 73186 (Nov. 29, 2011) (emphasis added). CMS also rejected deviating from its standard cost methodology and stated that it would be inappropriate to do so based on claims made by a handful of device manufacturers, who furnished only a portion of all cardiac monitoring services. The only item accepted as a direct, reimbursable cost by CMS was the cardiac telemetry monitoring device worn by the patient.

2. Defendants' Scienter Is Confirmed in the Delaware Litigation Between Bardy and Hill-Rom

184. On February 28, 2021, iRhythm's law firm of record in this Action filed a Verified Complaint on behalf of iRhythm's competitor, Bardy, against Hill-Rom in the Delaware Court of Chancery seeking to enforce a merger agreement between the two companies. According to the lawsuit, Hill-Rom gave Bardy notice that it would not close the merger because the new Novitas rates in 2021 had devastated Bardy's business and constituted a material adverse event that excused performance. The matter was tried over three days and involved substantial pre-trial and post-trial briefing, deposition testimony of 13 fact witnesses and 5 expert witnesses, and live testimony from 6 fact witnesses and 5 expert witnesses at trial. Much of the testimony focused on iRhythm because it was the largest seller of AECG devices.

185. In a post-trial brief, Bardy's lawyers agreed that "iRhythm's patch has been clinically shown to be far less reliable than the CAM patch both in terms of missing arrhythmias and misdiagnosing rhythm disorders in healthy patients." *Bardy Diagnostics, Inc. v. Hill-Rom, Inc.*, No. C.A. No. 2021-0175-JRS, Plaintiff's Post-Trial Br. at 6 (Del. Ch. May 26, 2021). In the same brief, Bardy's lawyers concurred that CMS' rate-setting process is "'iterative,' building upon prior analyses and input from stakeholders, who are given multiple opportunities to comment and 'educate' CMS," confirming the value and impact of the MCDA Reports. *Id.* at 13. Bardy relied on testimony to argue that rates initially listed in CMS' proposed rules are not significant because until a final rule is published "you don't know where CMS is ultimately going to land." *Id.* at 17 n.79 (Frank. Tr. 471:14-472:1).

186. Bardy further argued that Hill-Rom had assumed the risk of a rate cut during the notice-and-comment period in 2020 between the Proposed Rule and the Final Rule for calendar year 2021, because it hired a law firm and consultants such as David Parr, who warned that Novitas' pre-Class Period inflated rates were at risk, and projections based on one or two instances of outlier MAC pricing like Novitas' pre-Class Period rates for AECG services were a huge red flag. After the Final Rule for 2021 was announced in December 2020, Mr. Parr again correctly warned that there was a high risk that Novitas' rate structure would move to the mid-range when the CPT codes became permanent. Hill-Rom decided to move forward despite these warnings. However, Hill-Rom did renegotiate the merger price downwards, and linked earnout payments to revenue targets that would change depending on whether the MAC would cut rates, showing that all the players in the industry understood the risks involved here.

187. Evidence also emerged in this litigation that senior executives at Bardy believed that the industry had only one chance between January 2021 and April 2021 to convince Novitas to raise the rates. Defendants described the communications with Novitas as "constructive" and gave investors the false impression that the MAC was open to hearing the industry's views even after the April 2021 rate cuts, but they did not disclose that the industry believed that there was no hope for an increase after April 2021. *See Bardy Diagnostics, Inc. v. Hill-Rom, Inc.*, No. C.A. No. 2021-0175-JRS, Defendant's Post-Trial Br. at 26 (Del. Ch. May 26, 2021).

188. Expert testimony and internal emails between the most senior executives at Bardy also confirmed that cuts to reimbursement rates would necessarily have a negative impact on contracts with commercial payors as well. For instance, an internal Bardy document acknowledged that commercial payors would renegotiate rates as a multiple of the Medicare rate. *Id*. at 12-15. One witness confirmed the reality that "you don't see the effect [on commercial rates] playing out immediately" and you "would expect the effect to increase over time." *Id.* at 14 (Noether. Tr. 820:3-7). The witness further stated that peer-reviewed economic literature supported "the effect to happen over one to three years." *Id.* (Noether. Tr. 820:7-11).

189. Adi Renbaum, an expert who testified in support of Bardy, and was retained by iRhythm's current law firm that represents it in this Action, admitted that clinical value is relevant

only for determining whether to "establish coverage" or whether Medicare should cover the services at all, and that once coverage is established "public health arguments and clinical benefits of a particular service do not factor into the task of setting a reimbursement rate for that service." *Id*. at 41 (Renbaum. Tr. 344:7-11, 366:20-24). Ms. Renbaum further conceded that CMS sets rates based on the actual "costs incurred by the service providers," and that "the patch devices themselves are the single largest cost component of the CPT codes at issue." *Id.* (Renbaum. Tr. 334:21-335:17, 337:7-10). Ms. Renbaum also admitted that CMS "will not set national pricing for the CPT codes at issue without actual invoices reflecting the cost information for the patch devices themselves." *Id*. (Renbaum. Tr. 337:24-338:17).

190. Hill-Rom also relied on the testimony of a former Medical Director of Novitas, who said that "[p]ublic health arguments and clinical benefits support a coverage policy (i.e. why the service is appropriate and reimbursed). They do not factor into the 'mundane' task of pricing or valuing the service which comes from an understanding of how the service is rendered and what cost inputs are used." *Id.* at 43 (Querry. Tr. 218:12-21).

191. In addition, the CFO of Bardy, Mark Querry, testified that the cost of the patch itself was "trending down," corroborating the account of the senior executive quoted in the October 5, 2020 MCDA Report, and demonstrating that the industry had no incentive to produce an invoice at all. *Id.* at 42 (Querry. Tr. 184:15-19).

192. Finally, one of the key issues in the merger litigation was whether Bardy had been disproportionately impacted by the rate cuts compared to its peers, which would excuse Hill-Rom from completing the transaction. While the parties disputed the facts on this issue, experts on both sides compared whether the financial impact on Bardy was similar to the financial impact on iRhythm, and there was no dispute that both companies would be worthless from the perspective of the sum of all future cashflows if the rates persisted. Expert modelling in the merger litigation also revealed that iRhythm's revenues would decline 16% for Medicare payors and 60% if both Medicare payors and commercial payors were included in the calculations, effectively destroying its business if the rate cuts persisted.

3. That Defendants' Misrepresentations Involved iRhythm's Core Operations Bolsters Scienter

193. Between 95% to 97% of the Company's revenue is derived from the Zio devices, only 10% of which consisted of revenue received from the sale of Zio AT. Hence, Zio XT is the Company's core product, and it is inconceivable that Defendants would not know about the most significant risk impacting this product even before the Class Period began.

194. There can be no reasonable dispute that reimbursement rates for Zio XT were critical to the Company's viability throughout the Class Period. Modelling by experts retained in the Delaware Litigation between Bardy and Hill-Rom showed that iRhythm would run out of cash within the next few years if the rates set by Novitas in April 2021 did not change. Expert testimony in the Delaware Litigation further revealed that iRhythm's revenues would decline by 60% for all payors if Novitas or CMS did not increase the rates, effectively delivering a death blow to the Company's future.

195. The reimbursement rates set by CMS or the MAC were also of such critical importance to the Company's short term and long term prospects that it is highly unlikely that the Defendants here would not be aware: (a) of past CMS practice rejecting arguments similar to those they touted to investors; (b) that the cost of the Zio XT device itself was the single largest cost component of the CPT codes; or (c) that the Company was not entitled to inflate reimbursement rates by folding in SG&A and R&D expenses, even if they declined to produce detailed cost invoices.

4. Defendants Held Themselves Out as Knowledgeable About the Regulatory Landscape

196. Defendants' own statements show that they repeatedly held themselves out as extremely knowledgeable about the regulatory landscape, and CMS' and the MACs' cost methodology, rules, and practices. For example, on an August 4, 2020 conference call to discuss the Proposed Rule for 2021, King told investors that the Company "worked hand-in-hand with the various governing bodies, AMA, ACC, HRS, in drafting and constructing that code language. So we were well aware and well informed, and we think this best represents the interest of patients,

providers, service providers like ourselves in the industry." At this conference call, King also stated that iRhythm had provided CMS with claims data for the inflated reimbursement rates, which he falsely referred to as "invoices." On August 6, 2020, King told investors that the Company had "collaborated" with "CMS staff" for several years to convince the agency to endorse inflated reimbursement rates. King also discussed how CMS was required to operate a balanced budget format, demonstrating that he was familiar with its rules. On August 13, 2020, King again told investors that "we have a very long standing collaboration or history of collaboration with medical societies as well as CMS."

197. Similarly, Coyle told investors at an earnings conference call held in February 2021 that the Company had already had multiple meetings with Novitas, described the meetings as "very constructive," and claimed that Novitas was considering the differences between traditional ECG monitoring devices and the Zio XT, including "the increased cost components that go into being able to provide that significant clinical and economic advantage relative to" traditional monitoring devices. Coyle, however, did not disclose that iRhythm had included in the figures it provided Novitas inappropriate, indirect costs from Medicare, that clinical value is irrelevant to reimbursement rates, or that iRhythm had no incentive to provide a proper invoice with a breakdown of costs because the actual cost of the Zio XT was trending downwards. On the earnings conference call held in February 2021, Devine also spoke about the meetings with Novitas, and told investors that the Company emphasized the "cost differential" between traditional ECG monitoring devices and the Zio XT in meetings with Novitas.

198. On the April 12, 2021 conference call to discuss Novitas' revised reimbursement rates, Coyle told investors that the Company was "actively involved" with CMS and had met CMS in March 2021 to discuss reimbursement rates. On May 6, 2021, Coyle told investors that the Company had again met with Novitas after the revised rates were released in April 2021 and acknowledged that Novitas was laser focused on "cost inputs." Coyle also told investors again that "we continued to pursue national pricing with CMS," and that iRhythm had met with CMS in March 2021.

199. Given the Defendants' own statements, it is inconceivable that Defendants would not know, or did not recklessly disregard, that their misleading statements throughout the Class Period misled investors.

5. iRhythm's Reaction to the MCDA Reports Creates an Additional Inference of Scienter

200. As discussed above, iRhythm was fully aware of and submitted a three-page response to the October 5, 2020 MCDA Report in the notice-and-comment period between the release of the Proposed Rule and the Final Rule in 2020. In this letter, iRhythm did not dispute that it improperly sought reimbursement for prohibited indirect costs, including SG&A expenses and R&D expenses, and did not dispute that it had declined to provide invoice data to CMS that would substantiate a higher rate.

6. King's Insider Sales at Inflated Prices Enhance an Inference of Scienter

201. During the Class Period, King took advantage of iRhythm's artificially inflated stock price and earned approximately $18.816 million from sales of iRhythm common stock on the open market:

King's Class Period Stock Sales[1]:

Date	Shares Disposed	Price	Proceeds
8/12/2020	25,694	$178.7570	$4,592,982
8/12/2020	17,272	$179.5466	$3,101,129
8/12/2020	3,558	$181.1289	$644,457
8/12/2020	3,102	$181.9863	$564,522
8/12/2020	3,989	$181.7665	$725,067
8/12/2020	6,007	$184.0681	$1,105,697
11/12/2020	2,210	$251.8636	$556,619
11/12/2020	1,796	$252.4287	$453,362
11/12/2020	5,438	$254.4094	$1,383,478
11/12/2020	9,724	$255.1935	$2,481,502
11/12/2020	9,659	$256.1629	$2,474,277
11/12/2020	690	$257.2528	$177,504
11/12/2020	2,152	$258.2600	$555,776
Total	**91,291**		**$18,816,371**

[1] Excluded from these charts are proceeds from shares withheld by iRhythm in order to cover tax withholding obligations.

202. King sold 124,709 fewer shares of the Company's common stock during the Class Period than in the months preceding the Class Period when he sold 216,000 shares of common stock for proceeds of $20.57 million.

203. King also took advantage of the fact that, while the average price of the Company's common stock before the Class Period was $95.2412, the average price of the Company's common stock increased significantly to $206.1142 as Defendants misled investors repeatedly with their false statements.

LEAD PLAINTIFF'S CLASS ACTION ALLEGATIONS

204. Lead Plaintiff brings this action as a class action pursuant to Federal Rule of Civil Procedure 23(b)(3) on behalf of all persons or entities that purchased or otherwise acquired iRhythm's common stock between August 4, 2020 and July 13, 2021 (the "Class Period"), both dates inclusive. Excluded from the Class are Defendants, officers, and directors of iRhythm, any entity in which any of the Defendants (alone or in combination with other Defendants) have or had a controlling interest, and any affiliates, family members, legal representatives, heirs, successors or assigns of any of the above.

205. The Class is so numerous that joinder of all members is impracticable. Throughout the Class Period, iRhythm's common stock was actively traded on the NASDAQ under the ticker symbol "IRTC." An average monthly volume of 11.2 million shares traded during the Class Period. Lead Plaintiff believes that there are several hundred if not thousands of members in the proposed Class, with the overwhelming majority of Class members having held shares in a street name. Potential Class members may be identified from records maintained by iRhythm, its transfer agents, and brokers and banks that hold shares beneficially for investors in a street name and may be notified of the pendency of this action by mail, using the form of notice similar to that customarily used in securities class actions.

206. Lead Plaintiff's claims are typical of the claims of those of the Class, as all Class members were similarly affected by Defendants' wrongful conduct in violation of the federal laws complained of herein.

207. Lead Plaintiff will fairly and adequately protect the interests of the members of the Class and has retained counsel competent and experienced in class action and securities litigation.

208. Common questions of law and fact exist as to all Class members and predominate over any questions solely affecting individual Class members. Among the questions of law and fact common to the Class are:

A. whether iRhythm and the Individual Defendants made false and misleading statements or failed to disclose material information that rendered their Class Period statements misleading;

B. whether the Individual Defendants are control persons of iRhythm for purposes of Section 20(a) of the Exchange Act;

C. whether iRhythm and the Individual Defendants made the misrepresentations or omissions with scienter;

D. whether the federal securities laws were violated by Defendants' acts as alleged herein;

E. whether the prices of iRhythm's securities during the Class Period were artificially inflated because of the Defendants' misconduct complained of herein; and

F. whether the Class has sustained damages with respect to its Exchange Act claims and, if so, what is the proper measure of damages.

209. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy since joinder of all members is impracticable. Furthermore, as the damages suffered by individual Class members may be relatively small, the expense and burden of individual litigation make it impossible for Class members to individually redress the wrongs done to them. There will be no difficulty in the management of this action as a class action.

210. With respect to the Exchange Act claims, Lead Plaintiff will rely, in part, upon the presumption of reliance established by the fraud-on-the-market doctrine in that:

A. Defendants made public misrepresentations or failed to disclose material facts during the Class Period;

B. the omissions and misrepresentations were material;

C. iRhythm's common stock traded in an efficient market;

D. the Company's common stock was liquid and traded with moderate to heavy volume during the Class Period;

E. the Company traded on the NASDAQ, and was covered by multiple analysts;

F. the misrepresentations and omissions alleged would tend to induce a reasonable investor to misjudge the value of the Company's common stock; and

G. Lead Plaintiff and other Class members purchased or otherwise acquired iRhythm common stock between the time that the Defendants failed to disclose or misrepresented material facts, and the time that the true facts were disclosed or materialized, without knowledge of the omitted or misrepresented facts.

211. Based upon the foregoing, Lead Plaintiff and other Class members are entitled to a presumption of reliance upon the integrity of the market if they did not actually rely on Defendants' materially false or misleading statements.

212. Alternatively, Lead Plaintiff and the Class members are entitled to the presumption of reliance established by the Supreme Court in *Affiliated Ute Citizens of the State of Utah v. United States*, 406 U.S. 128 (1972), as Defendants omitted material information in violation of a duty to disclose such information, as detailed above.

COUNT I:

(Against Defendants iRhythm, King, Coyle and Devine for Violations of Section 10(b) and Rule 10b-5)

213. Lead Plaintiff repeats and realleges the allegations contained in Paragraphs 1 to 212 above as if fully set forth herein.

214. This Count is asserted against iRhythm and each of the Individual Defendants for violations of Section 10(b) of the Exchange Act, 15 U.S.C. § 78j(b), and Rule 10b-5 promulgated thereunder by the SEC.

215. During the Class Period, Defendants engaged in a plan, scheme, conspiracy and course of conduct, pursuant to which they knowingly or recklessly engaged in acts, transactions, practices and courses of business which operated as a fraud and deceit upon the Lead Plaintiff and the other members of the Class; made various untrue statements of material fact and omitted to state material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading; and employed devices, schemes and artifices to defraud in connection with the purchase and sale of securities. Such scheme was intended to, and, throughout the Class Period, did: (i) deceive the investing public, including the Lead Plaintiff and other Class members, as alleged herein; (ii) artificially inflate and maintain the market price of iRhythm common stock; and (iii) cause Lead Plaintiff and other members of the Class to purchase or otherwise acquire iRhythm common stock at artificially inflated prices.

216. Specifically, iRhythm and the Individual Defendants made material misrepresentations and omitted to disclose material information that rendered their statements misleading as particularized in Paragraphs 147 through 178.

217. The Individual Defendants had actual knowledge of the materially false and misleading statements and material omissions alleged herein and intended thereby to deceive the

Lead Plaintiff and the other members of the Class, or, in the alternative, acted with reckless disregard for the truth in that they failed or refused to ascertain and disclose such facts as would reveal the materially false and misleading nature of the statements made, although such facts were readily available to iRhythm and the Individual Defendants. In addition to the facts alleged herein demonstrating a strong inference of scienter, certain information showing that Defendants acted knowingly or with reckless disregard for the truth is peculiarly within these Defendants' knowledge and control. As the senior managers of iRhythm, the Individual Defendants had knowledge of the details of iRhythm's internal affairs that were inconsistent with their public statements.

218. As officers and directors of a publicly held company, the Individual Defendants had a duty to disseminate timely, accurate, and truthful information regarding iRhythm's business, operations, and finances. As a result of the dissemination of the aforementioned false and misleading statements, the market price of iRhythm common stock was artificially inflated throughout the Class Period. Additionally, as a seller of iRhythm common stock during the Class Period, King had a duty to disclose or refrain from trading on iRhythm's artificially inflated stock price.

219. In ignorance of the adverse facts concerning iRhythm's business, operations, and finances, which were concealed by the misrepresentations and omissions alleged herein, Lead Plaintiff and the other members of the Class purchased or otherwise acquired iRhythm common stock at artificially inflated prices and relied upon the price of the common stock, the integrity of the market for the common stock or upon statements disseminated by Defendants and were damaged thereby.

220. During the Class Period, iRhythm's common stock was traded on an active and efficient market. Lead Plaintiff and the other members of the Class, directly relying on the materially false and misleading statements described herein, or relying upon the integrity of the

market, purchased, or otherwise acquired shares of iRhythm at prices artificially inflated by Defendants' wrongful conduct. Had Lead Plaintiff and the other members of the Class known the truth, they would not have purchased or otherwise acquired said common stock or would not have purchased or otherwise acquired it at the inflated prices that were paid. At the time of the purchases or acquisitions by Lead Plaintiff and the Class, the true value of iRhythm's common stock was substantially lower than the prices paid by Lead Plaintiff and the other members of the Class. The market price of iRhythm's common stock declined sharply upon public disclosure of the facts or materialization of the risks alleged herein to the injury of Lead Plaintiff and other Class members.

221. By reason of the conduct alleged herein, iRhythm and the Individual Defendants knowingly or recklessly violated Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder.

222. As a direct and proximate result of these Defendants' wrongful conduct, Lead Plaintiff and the other Class members suffered damages in connection with their respective purchases of the Company's common stock during the Class Period when the risk of Defendants' wrongdoing materialized or upon the disclosure thereof, causing the price of iRhythm common stock to decline. iRhythm and the Individual Defendants are liable for damages in connection with these losses under Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder.

COUNT II:

(Against Defendants King, Coyle and Devine for Violations of Section 20(a) of the Exchange Act)

223. Lead Plaintiff repeats and realleges the allegations contained in Paragraphs 1 to 222 above, as if fully set forth herein.

224. During the Class Period, the Individual Defendants participated in the operation and management of iRhythm, and conducted and participated, directly and indirectly, in the conduct of

iRhythm's business affairs. Because of their senior positions, they knew the adverse non-public information that rendered iRhythm's public statements false and misleading.

225. As officers and directors of a publicly owned company, the Individual Defendants had a duty to disseminate accurate and truthful information with respect to iRhythm's financial information and results of operations, and to correct promptly any public statements issued by iRhythm, which had become materially false or misleading.

226. Because of their positions of control and authority as senior officers, the Individual Defendants were able to, and did, control the Company's statements, which iRhythm disseminated in the marketplace during the Class Period concerning iRhythm's financial information and business. King served as the Company's CEO until January 12, 2021, and he was directly involved in the day-to-day management of the Company, including direct communications with analysts and investors in conference calls where he made false and misleading statements identified in Paragraphs 147 through 167. Coyle served as the Company's CEO from January 12, 2021 to June 1, 2021, and similarly managed the Company's day-to-day affairs, including direct communications with analysts and investors where he made the false and misleading statements identified in Paragraphs 168 through 174. Devine served as the Company's CFO from June 2020 to June 2021, was involved in its day-to-day to management, and signed and certified the misleading Annual Report identified in Paragraph 170. Between June 1, 2021 and July 13, 2021, Devine also served as the Company's CEO and made the false and misleading statements in direct response to pointed analyst questions identified in Paragraphs 175 through 178.

227. Throughout the Class Period, the Individual Defendants exercised their power and authority to cause iRhythm to engage in the wrongful acts complained of herein. The Individual Defendants, therefore, were "controlling persons" of iRhythm within the meaning of Section 20(a)

of the Exchange Act. In this capacity, they participated in the unlawful conduct alleged which artificially inflated the market price of iRhythm's common stock.

228. The Individual Defendants, therefore, acted as controlling persons of iRhythm. By reason of their senior management positions and/or being directors of iRhythm, the Individual Defendants had the power to direct the actions of, and exercised the same to cause, iRhythm to engage in the unlawful acts and conduct complained of herein. The Individual Defendants exercised control over the general operations of iRhythm and possessed the power to control the specific activities, which comprise the primary violations about which Lead Plaintiff, and the other members of the Class, complain.

229. As control persons, the Individual Defendants are liable pursuant to Section 20(a) of the Exchange Act for the primary violations of the Exchange Act committed by iRhythm.

PRAYER FOR RELIEF

WHEREFORE, Lead Plaintiff demands judgment against Defendants as follows:

A. Determining that the instant action may be maintained as a class action under Rule 23 of the Federal Rules of Civil Procedure, and certifying Lead Plaintiff as the Class Representative;

B. Requiring Defendants to pay damages sustained by the Lead Plaintiff and the Class by reason of the acts and transactions alleged herein;

C. Awarding Lead Plaintiff and the other members of the Class prejudgment and post-judgment interest, as well as their reasonable attorneys' fees, expert fees, and other costs; and,

D. Awarding such other and further relief as this Court may deem just and proper.

DEMAND FOR TRIAL BY JURY

Lead Plaintiff hereby demands a trial by jury.

Dated: August 2, 2021

POMERANTZ LLP

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CERTIFICATE OF SERVICE

I hereby certify that on August 2, 2021, a copy of the foregoing was filed electronically via the Court's CM/ECF system. Notice of this filing will be sent by e-mail to all parties by operation of the Court's electronic filing system. Parties may access this filing through the Court's CM/ECF System.

POMERANTZ LLP

By: */s/Omar Jafri*
Omar Jafri

Co-Lead Counsel